

EXPRESS MAIL NO.: EV 531 712 866 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:

Ensoli

Attorney Docket No.:

11340-007-999

International (PCT) Application No.:

PCT/EP02/04303

Filed:

April 18, 2002

Title:

USE OF HIV-PROTEASE INHIBITORS
TO BLOCK CELL MIGRATION AND/OR
INVASION, TISSUE INFILTRATION
AND OEDEMA FORMATION**PETITION FOR REVIVAL OF AN INTERNATIONAL APPLICATION
FOR PATENT DESIGNATING THE UNITED STATES
ABANDONED UNINTENTIONALLY UNDER 37 C.F.R. § 1.137(b)**

Attention: PCT Legal Staff

Mail Stop PCT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

The above-identified international patent application became abandoned as to the United States because the fees and documents required by 35 U.S.C. § 371(c) were not filed prior to the expiration of the time set in 37 C.F.R. §§ 1.495(b) or (c) as applicable. The date of abandonment is October 19, 2003, which is the day after the date on which the 35 U.S.C. § 371(c) requirements were due. See 37 C.F.R. § 1.495(h).

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION.

NOTE: A grantable petition requires the following items:

- (1) Petition fee;
- (2) Proper reply;
- (3) Terminal disclaimer with disclaimer fee which is required for all international applications having an international filing date before June 8, 1995; and
- (4) Statement that the entire delay was unintentional.

09/29/2005 HKAYPAGH 00000109 503013 10349958

01 FC:2453

750.00 DA

1. Petition fee

☒ Small entity - fee \$750.00 (37 C.F.R. § 1.17(m)). Applicant claims small entity status. See 37 C.F.R. § 1.27.

☐ Other than small entity - fee \$1,500.00 (37 C.F.R. § 1.17(m)).

2. Proper reply

- A. The proper reply (the missing 35 U.S.C. § 371(c) requirement(s)) in the form of
- (1) a Transmittal Letter to the United States Designated/Elected Office (DO/EO/US)(Form PTO-1390);
 - (2) a declaration of the inventor;
 - (3) a copy of WO 02/087583 A3; and
 - (4) a Preliminary Amendment.

☐ has been filed previously on _____.

☒ is enclosed herewith.

3. Terminal disclaimer with disclaimer fee

☒ Since International Application No. PCT/EP02/04303 has an international filing date on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 C.F.R. § 1.20(d)) of \$ _____ for a small entity or \$ _____ for other than a small entity) disclaiming the required period of time is enclosed herewith (see PTO/SB/63).

4. Statement

The above-identified international patent application, No. PCT/EP02/04303 (hereinafter "the International Application"), was filed on April 18, 2002 and claims priority to Italian Patent Application No. RM2001A000210, filed April 18, 2001. Through inadvertent error constituting a mistake in fact, the U.S. national stage of the International Application was not timely filed by thirty months from the claimed priority date, *i.e.*, October 18, 2003. Applicant submits that the entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 C.F.R. § 1.137(b) was unintentional based on a mistake in fact. The facts in support of this petition are provided below.

Applicant submits herewith several pieces of correspondence between Istituto Superiore di Sanità (hereinafter "ISS") and the Italian law firm of Notarbartolo & Gervasi (hereinafter "N&G") and between or among ISS employees and consultants that evidence the intention of ISS to timely file a U.S. national stage of the International Application. ISS is the Assignee of the entire right, title and interest in the International Application by virtue of

Italian national law R.D. 29 giugno 1939, n.1127, which was in existence at the time of filing Italian Patent Application No. RM2001A000210, to which the International Application claims priority. Specifically, Italian national law R.D. 29 giugno 1939, n.1127 mandates that ownership of inventions made by an employee, *i.e.*, Dr. Ensoli, during employment by execution of an employment contract belongs to the employer, *i.e.*, ISS. ISS is also the Assignee of the entire right, title and interest in the U.S. national stage of International Application by virtue of an assignment from the inventor Dr. Barbara Ensoli (a copy of the assignment is enclosed herewith as Exhibit 1). ISS had previously retained the service of N&G to handle the International Application. Specifically, the enclosed copies of correspondence between ISS and N&G consist of the following:

- (1) a letter dated September 16, 2003 from Dr. Martoccia (Director General of Administrative Services and Financial Affairs, which the ISS office that handles patent matter ("ISS Patent Office") is part thereof) to Dr. Ensoli (see Exhibit 2);
- (2) a letter dated September 17, 2003 from Dr. Ensoli to Dr. Martoccia (see Exhibit 3);
- (3) a letter dated September 24, 2003 from Dr. Martoccia to N&G (see Exhibit 4);
- (4) a letter dated September 30, 2003 from Dr. Ensoli to Dr. Martoccia (see Exhibit 5);
- (5) a letter dated October 14, 2003 from Dr. Martoccia to N&G, copying Dr. Ensoli (see Exhibit 6);
- (6) four e-mails dated between October 27, 2003 and November 6, 2003 between and among ISS and N&G personnel (see Exhibit 7); and
- (7) a letter dated October 31, 2003 from Dr. Ensoli to Dr. Martoccia (see Exhibit 8).

A certified English translation of each piece of correspondence is also included in the respective exhibits. In addition, Applicant submits concurrently herewith a Declaration by Dr. Giovan Battista Cozzone (hereinafter "Cozzone Declaration"), who holds the position of the Board Advisor for Intellectual Property & Technology at ISS and is responsible for coordinating with N&G the filing of the national stage applications of the International Application (see Cozzone Declaration, ¶¶1 and 2). Applicant submits that the exhibits and Cozzone Declaration together demonstrate that ISS intended to enter the U.S. national phase, but, through inadvertent error constituting a mistake in fact, did not file the documents to do

so by the due date.

In a letter dated September 8, 2003 addressed to Dr. Martoccia, Ms. Primiceri (of N&G) enclosed a copy of the International Preliminary Examination Report ("IPER") issued on July 29, 2003 for the International Application and reminded Dr. Martoccia that the last date to enter the national phase in the countries of interest would expire on October 18, 2003 and requested that instructions for national phase entry be provided to N&G by September 15, 2003 (see Cozzone Declaration, ¶3).

As shown in the certified English translation in Exhibit 2, in a letter dated September 16, 2003 addressed to Dr. Ensoli (the inventor), Dr. Martoccia enclosed a copy of Ms. Primiceri's letter dated September 8, 2003 and stressed the urgency of providing instructions in response to Ms. Primiceri's letter.

As shown in the certified English translation in Exhibit 3, in her reply letter dated September 17, 2003 addressed to Dr. Martoccia, Dr. Ensoli expressed interest in proceeding with the national phase in the countries of interest by the deadline of October 18, 2003. Exhibit 3 has been redacted to delete information not related to this Petition.

In the meantime, in an e-mail dated September 15, 2003, Dr. Cozzone informed Ms. Rossetti that he planned to discuss the International Application with the inventor and others who are involved with the International Application and would provide instructions to N&G on national phase entry before September 25, 2003 (see Cozzone Declaration, ¶4).

In order to facilitate a discussion with the inventor and others involved with the International Application regarding in which countries to enter national phase, Dr. Cozzone telephoned the attorneys at N&G on September 19, 2003 and requested that cost estimates for filing national stage applications of the International Application be provided to the ISS Patent Office (see Cozzone Declaration, ¶5).

On September 22, 2003, Dr. Cozzone received an e-mail from Ms. Rossetti (of N&G), copying Dr. Ensoli (the inventor), which enclosed a copy of a letter dated September 22, 2003 from Ms. Gerli (of N&G) to Dr. Martoccia (see Cozzone Declaration, ¶6). In her letter dated September 22, 2003, Ms. Gerli provided cost estimates for entering the national phase in countries including, inter alia, the United States, and requested that instructions to enter national phases be provided by September 25, 2003 (see Cozzone Declaration, ¶6).

On September 23, 2003, Dr. Cozzone, Dr. Ensoli, and others involved with the International Application discussed the International Application and agreed that ISS should proceed with the national stage applications (see Cozzone Declaration, ¶7).

As shown in the certified English translation in Exhibit 4, in her letter dated

September 24, 2003 addressed to N&G, Dr. Martoccia confirmed to N&G ISS' interest to proceed with the International Application. Exhibit 4 has been redacted to delete information not related to this Petition.

Also, as shown in the certified English translation in Exhibit 5, in her letter dated September 30, 2003 addressed to Dr. Martoccia, Dr. Ensoli again stressed her intention to proceed with the national phase of the International Application by October 18, 2003. The letter included a table of countries, including the United States, for which a detailed cost estimate was to be prepared by N&G.

Also, on September 30, 2003, Dr. Cozzone wrote an e-mail to Ms. Rossetti (of N&G), copying Dr. Ensoli, Ms. Primiceri (of N&G), and Dr. Martoccia, asking for a more detailed breakdown of the costs for filing the national stage applications of the International Application (see Cozzone Declaration, ¶8).

In response, in an e-mail dated September 30, 2003, Ms. Gerli informed Dr. Cozzone that the detailed cost breakdown could not be provided before the October 18, 2003 deadline (see Cozzone Declaration, ¶9). Nevertheless, Dr. Cozzone indicated in a reply e-mail dated October 1, 2003 that it was not indispensable to have the detailed cost breakdown by the October 18, 2003 deadline because that information was not necessary for ISS to determine whether to file national stage applications of the International Application (see Cozzone Declaration, ¶10).

As shown in the certified English translation in Exhibit 6, pursuant to Dr. Ensoli's request in a letter dated September 30, 2003 and in a letter dated October 14, 2003 addressed to N&G and copying Dr. Ensoli, Dr. Martoccia requested that N&G provide a detailed breakdown of the cost estimates for entering the national phases in an enclosed table of countries, including the United States.

Dr. Cozzone then asked Dr. Ensoli (the inventor) to provide instructions to the ISS Patent Office regarding in which countries the national phase of the International Application was to be entered (see Cozzone Declaration, ¶11).

As shown on pages 3-6 of the certified English translation in Exhibit 7, in an e-mail dated October 27, 2003 denoted with high priority and addressed to Ms. Gerli (of N&G) and copying Ms. Primiceri (of N&G) and Dr. Cozzone (see Cozzone Declaration, ¶12), Ms. Paola Sergiampietri (Dr. Ensoli's secretary), on behalf of Dr. Ensoli, confirmed her intention to proceed with the filing of national stage applications in connection with the International Application and to provide cost estimates for entering the national phase in certain designated countries not already included in Ms. Gerli's letter dated September 22, 2003 (identified as

“PATENT PI” under N&G reference number “2770PTWO/er”) (see page 4, lines 6-8 of the certified English translation in Exhibit 7).

In response to Dr. Ensoli’s e-mail dated October 27, 2003, Ms. Gerli sent a reply e-mail dated October 30, 2003 (see pages 1-3 of the certified English translation in Exhibit 7) addressed to Dr. Ensoli and copying Ms. Primiceri, in which, *inter alia*, Ms. Gerli indicated that she had never received Dr. Ensoli’s letter dated September 30, 2003 (see page 2, lines 1-2 of the certified English translation in Exhibit 7). In her e-mail dated October 30, 2003, Ms. Gerli also inquired as to whether the filing of the U.S. national stage of the International Application was to be entrusted to the U.S. law firm of Pennie & Edmonds LLP (hereinafter “P&E”) (see page 3, lines 7-11 of the certified English translation in Exhibit 7). Finally, in her e-mail dated October 30, 2003, Ms. Gerli reminded Dr. Ensoli that the time for entry in the U.S. national stage for the International Application had expired and could be recovered through the filing of a petition (see page 3, lines 12-15 of the certified English translation in Exhibit 7).

In an e-mail dated October 30, 2003, Dr. Cozzone advised Dr. Martoccia, Ms. Sergiampietri (Dr. Ensoli’s secretary), and Dr. Ensoli (the inventor) that the U.S. law firm of Pennie & Edmonds LLP (hereinafter “P&E”) should be entrusted with the U.S. national stage of the International Application (see Cozzone Declaration, ¶13). Thus, this e-mail was meant to inform Dr. Martoccia that ISS should instruct N&G to request P&E to file the U.S. national stage application (see Cozzone Declaration, ¶13).

As shown in the certified English translation in Exhibit 8, in view of Dr. Cozzone’s suggestion in his e-mail dated October 30, 2003, Dr. Ensoli informed Dr. Martoccia in a letter dated October 31, 2003 that the U.S. national stage of the International Application must be entrusted to P&E and requested that the ISS Patent Office instruct N&G accordingly.

In another e-mail dated November 6, 2003 addressed to Ms. Rossetti (N&G) and copying Dr. Martoccia, Dr. Ensoli and Ms. Sergiampietri, all of ISS, Dr. Cozzone indicated that he had already informed ISS that P&E should be entrusted with the filing of the U.S. national stage of the International Application and that the ISS Patent Office would be sending N&G instructions to that effect later in the day (see Cozzone Declaration, ¶14).

However, contrary to what Dr. Cozzone believed to have communicated to Dr. Martoccia, the ISS Patent Office did not ask N&G to instruct P&E to file the U.S. national stage of the International Application (see Cozzone Declaration, ¶15). Instead, in a letter dated November 6, 2003, Dr. Martoccia asked N&G to file the national stage applications in all the designated countries except in the U.S. and informed N&G that ISS would directly

instruct P&E to file the U.S. national stage application of the International Application (see Cozzone Declaration, ¶15).

The ISS Patent Office misunderstood Dr. Cozzone's instructions (see Cozzone Declaration, ¶16). As a result, Dr. Martoccia issued inadvertently mistaken instructions regarding the U.S. national stage application to N&G and, as a result, N&G did not instruct P&E to file the U.S. national stage application of the International Application (see Cozzone Declaration, ¶16). Dr. Cozzone, who was under the assumption that, pursuant to his e-mail dated November 6, 2005, the ISS Patent Office would instruct N&G to instruct P&E to file the U.S. national stage application, also did not instruct P&E to file the U.S. national stage application (see Cozzone Declaration, ¶16). Therefore, P&E never received instructions from ISS to file the U.S. national stage of the International Application.

The failure to file the U.S. national stage application of the International Application was not recognized until after Dr. Cozzone had instructed the U.S. law firm of Jones Day (hereinafter "JD") to take over the files of the national stage applications of the International Application in December of 2004 and after the attorneys at JD had had a chance to review the files of the national stage applications by March of 2005 (see Cozzone Declaration, ¶17).

After reviewing the files of the national stage applications of the International Application provided by N&G, Dr. Margaret Brivanlou (an attorney currently at JD and previously at P&E prior to January 1, 2004) informed Dr. Cozzone, in a letter dated March 1, 2005 copying Dr. Ensoli (the inventor) and Dr. Adriane Antler and Ms. Ann Chen (also attorneys currently at JD and previously at P&E prior to January 1, 2004), that the file transfer had been completed and asked for confirmation that no U.S. national stage of the International Application had been filed (see Cozzone Declaration, ¶18).

In response to Dr. Brivanlou's letter dated March 1, 2005, Ms. Stefania Ceccarelli (of Dr. Ensoli's office) indicated in an e-mail dated March 4, 2005 addressed to Dr. Brivanlou and copying Dr. Cozzone, Dr. Antler and Ms. Chen that in 2003 ISS had started internal procedures to have P&E file the U.S. national stage of the International Application and that ISS would investigate whether such U.S. national stage application had ever been filed. A copy of Ms. Ceccarelli's e-mail dated March 4, 2005 is enclosed as Exhibit 9.

In view of Ms. Ceccarelli's e-mail, attorneys at JD also reviewed their files relating to ISS matters. In an e-mail dated March 10, 2005 addressed to Dr. Cozzone and copying Ms. Ceccarelli, Dr. Antler and Ms. Chen, Dr. Brivanlou confirmed that no correspondence had been located regarding instructions to P&E (the ISS files from P&E had been transferred to JD when Dr. Antler, Dr. Brivanlou and Ms. Chen had moved to JD) from either N&G or ISS

to file the U.S. national stage of the International Application. A copy of Dr. Brivanlou's e-mail dated March 10, 2005 is enclosed as Exhibit 10. Exhibit 10 has been redacted to delete information not related to this Petition.

By an e-mail dated March 28, 2005 to Dr. Antler, Dr. Cozzone discussed the circumstances that resulted in the U.S. national stage application not being timely filed (see Cozzone Declaration, ¶18). As described hereinabove, Dr. Cozzone explained that the ISS Patent Office had misinterpreted his instructions to ask N&G to appoint P&E as the U.S. correspondent to handle the filing of the U.S. national stage of the International Application, and thus, P&E never received instructions from either N&G or ISS to file the U.S. national stage of the International Application (see Cozzone Declaration, ¶¶15-16). Dr. Cozzone further explained that since he was not copied on the letter of instructions from the ISS Patent Office to N&G, he was not aware of this omission until after receiving Dr. Brivanlou's letter dated March 1, 2005 (see Cozzone Declaration, ¶¶15 and 18).

Upon investigation, Dr. Cozzone confirmed to Dr. Antler (of JD) in an e-mail dated March 28, 2005 that the omission to enter the U.S. national stage of the International Application had indeed occurred and authorized the attorneys at JD to begin preparing a petition to revive the abandoned U.S. national stage application (see Cozzone Declaration, ¶18). Dr. Cozzone then further investigated and assisted in collecting documents that evidence ISS's intention to timely file the U.S. national stage application of the International Application, and provided such documents to the attorneys at JD for preparation of this Petition (see Cozzone Declaration, ¶19).

In a letter dated April 15, 2005 addressed to Dr. Brivanlou and copying Dr. Cozzone and Dr. Antler and Ms. Chen, Dr. Ensoli enclosed several pieces of correspondence and certified English translations thereof regarding ISS's instructions to file the U.S. national stage of the International Application. The enclosures from Dr. Ensoli's letter dated April 15, 2005 appear in Exhibits 7 and 8 in this Petition and Exhibit J of the Cozzone Declaration.

ISS also collected and provided documents to JD (Attorneys for Applicant) in support of this Petition. The April 15, 2005 letter was received by Attorneys for Applicant on April 18, 2005. After reviewing the April 15, 2005 letter, and its enclosures, Attorneys for Applicant discovered that the certified English translation for one of the pieces of e-mail correspondence was incomplete. As a result, in a letter dated May 3, 2005 from Ms. Chen addressed to Dr. Ensoli and to the attention of Ms. Ceccarelli and copying Dr. Cozzone and Dr. Antler and Dr. Brivanlou, Ms. Chen requested that a complete certified English translation of said correspondence be furnished.

In response to Ms. Chen's request, Ms. Ceccarelli enclosed a copy of the complete certified English translation of said correspondence in a facsimile letter dated May 18, 2005 addressed to Dr. Brivanlou. The enclosure from Ms. Ceccarelli's facsimile letter dated May 18, 2005 appears in Exhibit H of the Cozzone Declaration.

Upon receipt of the May 18, 2005 facsimile letter, Attorneys for Applicant promptly commenced the drafting of the instant Petition. However, during the preparation of the instant Petition, Attorneys for Applicant realized that additional information and documents were desired. As a result, during a meeting in Italy with Dr. Cozzone and Dr. Ensoli on May 25, 2005, Dr. Antler and Dr. Brivanlou requested that these additional documents be provided with certified English translations.

In the meantime, based on their understanding of the correspondence between ISS and N&G, Dr. Brivanlou and Ms. Chen telephoned Ms. Gerli of N&G on June 1, 2005 to inquire about and confirm certain details relating to the failure to file the U.S. national stage application. Additional information was provided by Ms. Gerli in a e-mail dated June 6, 2005 addressed to Dr. Brivanlou.

Subsequently, Ms. Chen forwarded Ms. Gerli's e-mail dated June 6, 2005, and its attachments, to Ms. Ceccarelli in an e-mail dated June 9, 2005 and requested that certified English translations of the attachments be provided. On June 17, 2005, Attorneys for Applicant received from Ms. Ceccarelli the additional documents and certified English translations of a portion of the documents attached in Ms. Gerli's e-mail dated June 6, 2003.¹ On July 25, 2005, Attorneys for Applicant received from Ms. Ceccarelli certified English translations of the remaining documents attached in Ms. Gerli's e-mail dated June 6, 2003, except for those already in the possession of Attorneys for Applicant.² Upon receipt of these documents, Attorneys for Applicant promptly updated and filed the instant Petition.

Attorneys for Applicant submit that based on the above-discussed facts, through inadvertent error based on a mistake in fact, the materials and fee required by 35 U.S.C. § 371(c) and 37 C.F.R. § 1.495 were not timely filed in the United States Patent and Trademark Office, even though ISS intended to file the U.S. national stage of the International Application by the relevant deadline. Attorneys for Applicant further submit that any additional delay that resulted after the discovery of Applicant's failure to file the U.S.

¹ These documents appear in Exhibits 2-4 and 6 of this Petition and Exhibits B and D of the Cozzone Declaration.

² These documents appear in Exhibits C and E-G of the Cozzone Declaration.


national stage of the International Application to the filing of the instant Petition was due to efforts to obtain documents and English translations thereof that evidence the intention of ISS to timely file a U.S. national stage of the International Application and the mistake in fact that occurred whereby the U.S. national stage was not timely filed. Applicant submits that the entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 C.F.R. § 1.137(b) was unintentional.

Please charge the required fee(s), estimated to be \$750.00 (small entity), to Jones Day Deposit Account No. 50-3013. A copy of this sheet is enclosed for accounting purposes.

Applicant respectfully requests the granting of this petition, and the entry of the above-made remarks and enclosed materials into the file of the U.S. national stage of the International Application.

Respectfully submitted,

Date: September 15, 2005


Adriane M. Antler (Reg. No.) 32,605
JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939

Enclosures

10/549958

EXHIBIT 1 JC17 Rec'd PCT/PTO 15 SEP 2005

10/549958
EXHIBIT 2 JC17 Rec'd PCT/PTO 15 SEP 2005



MINISTERO DELLA SANITÀ

Istituto Superiore di Sanità

10/549958
16 SETTEMBRE 2003 Mod. 2101
JC17 Rec'd PCT/PTO 15 SEP 2005
00161 Roma
VIALE REGINA ELENA, 299
TELEGRAMMI: ISTISAN-ROMA
TELEX: 06610071
TELEFAX: 0649387118

N. 44217/SA 67
Risposta al Foglio del
N. _____
Allegati _____

DOTT.SSA BARBARA ENSOLI
LAB. VIROLOGIA
SEDE

OGGETTO: Domanda di brevetto Internazionale n. PCT/EP02/04303, depositata il 18.04.2002
"Use of inhibitors of protease of the Human immunodeficiency virus (HIV) ...".

Si trasmette, per il seguito di competenza, in allegato copia della nota della
Notarbartolo & Gervasi in data 08.09.2003, relativa al brevetto indicato in oggetto,
unitamente agli allegati ivi citati.

Si sottolinea l'urgenza in considerazione del fatto che la Società scrivente attende
disposizioni da questa Direzione entro il 15.09.2003.

IL DIRETTORE DEGLI AFFARI AMMINISTRATIVI E
DELLE RISORSE ECONOMICHE
(Dott.ssa R.M. MARTOCIA)

*Spese dirette
Ministero*

*Si prega di inviare per ogni lettera un solo esemplare e indicare nella risposta
il N. di protocollo a cui si risponde*



10/549958

JC17 Rec'd PCT/PTO 15 SEP 2005

SET OF FORMS
Health - 278

MOD. 2101

00161 Rome, 16 September 2003

Viale Regina Elena, 299

Telegram: ISTISAN-ROMA

Telex: 06610071

Telephone: 0649387118

[STAMP]

MINISTRY OF HEALTH

ISTITUTO SUPERIORE DI SANITA'

N°: 44217/SA67

Reply to the File of the:

N°: [...]

Enclosures: [...]

DOCTOR BARBARA ENSOLI
VIROLOGY LAB
MAIN OFFICE

Re: International patent request n. PCT/EP02/04303, deposited on the 18.04.2002 "Use of inhibitors of protease of the Human immunodeficiency virus (HIV) ..".

A copy of Notarbartolo & Gervasi's report, dated 08.09.2003, concerning the above mentioned patent is herein enclosed, for the part of Your competence, together with the enclosures therein specified.

The urgency of the matter is stressed in consideration of the fact that the Company writing is expecting instructions from the Direction within the 15.09.2003.

THE DIRECTOR OF FINANCIAL AFFAIRS AND ECONOMIC RESOURCES

(Doctor R. M. MARTOCCIA)

[Illegible signature]

[Specify nationalisation dates (hand-written)]

[IN THE MARGIN] You are kindly requested to mention only one subject per letter and to specify the N. of the File You are replying to.

JC17 Redacted 15 SEP 2005

T. B. A. L. L. O M A

Ufficio di Notari - Perizie e Traduzioni

VERBALE DI GIURAMENTO

CRONOLOGICO

N. 6510

Roma, 09 GIU. 2005

Addi 09.6.10.2005..... avanti al sottoscritto Cancelliere è presente il

Signor: GIANNINI Gioiù

documento: P.A. N. RM 6089390 M

rilasciato da MCTC-RM il 28/08/2002

il quale chiede di asseverare con giuramento il suesposto atto. Io
Cancelliere, previa ammonizioni di legge, invito il comparente al
giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente
adempiuto all'incarico affidatomi a conoscere la verità".

Letto confermato e...

Giovanna Dionette

IL DIRETTORE DI CANCELLERIA
(Giovanna Dionette)



[Handwritten signature]

APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da GIOVANNA DIONETTE

Agente in qualità di DIRETTORE DI CANCELLERIA

È segnato dal contrassegno/timbro Tribunale Ordinario di Roma

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma

In data - 9 GIU. 2005 e sotto il N. 1225/5 del Reg. delle Apostille

con sigillo dell'Ufficio legalizzazioni. IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE

Dott. Ferdinando Correale



EXHIBIT 3

10/549958

JC17 Rec'd PCT/PTO 15 SEP 2005



Istituto Superiore di Sanità

JC17 Rec'd PCT/PTO 15 SEP 2003



00161 Roma 14 03

VIALE REGINA ELENA, 299
TELEFONO: 06 48801
TELEFAX: 06 48807118
http://www.iss.it

Dott.ssa Rosa M. Martoccia
Dirigente dei Servizi
Amministrativi
SEDE

Oggetto: Domanda di brevetto internazionale n. PCT/EP02/04303 del 18.04.2002
Inventore: Dr. Barbara Ensoli
Rif. N&G: 2770PTWO/er

In riferimento alla comunicazione dell' 8/09/2003 della Società Notarbartolo & Gervasi S.p.A., e

si manifesta l'urgenza e l'interesse al proseguimento
REDACTED

REDACTED

Si comunica altresì l'interesse a proseguire con le fasi nazionali nei Paesi di nostro interesse (scadenza 18/10/03).

Dott.ssa Barbara Ensoli
Laboratorio di Virologia
SEDE

ISS STAMP

Mod. 2208
JC17 Rec'd PCT/PTO 15 SEP 2005

MIN. OF HEALTH
STAMP

00161 Rome, 17 September 2003
Viale Regina Elena 299
Telegram: ISTISAN ROMA
Telephone: 06 49801
Telex: 06 49387118
<http://www.iss.it>

Doctor Rosa M. Martocchia
Manager of Financial Services
MAIN OFFICE

Re: International patent application n. PCT/EP02/04303 of the 18.04.2002
Inventor: Doctor Barbara Ensoli
Ref. N&G: 2770PTWO/er

With reference to the letter of the 08/09/2003 from the Company "Notarbartolo & Gervasi S.p.A.",

REDACTED

pursue said application :

REDACTED

, we express the urgency and interest to

We furthermore communicate the interest to proceed with the national phases in the Countries of our interest (expiry 18/10/03).

Doctor Barbara Ensoli
Virology Lab
MAIN OFFICE
[illegible signature]

TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

CRONOLOGICO

N. **6510**

Roma **9 GIU. 2005**...

IL COLLABORATORE

Addi **09 GIU. 2005**, avanti al sottoscritto Cancelliere è presente il

Signor: **GIANNINI GIULIO**

documento: **P.A.** N. **RM 608939017**

rilasciato da **MCTC-RM** il **28/08/2002**

il quale chiede di asseverare con giuramento il **suesteso** atto. Io

Cancelliere, previe ammonizioni di legge, invito il comparente al

giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente

adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

La lettura è confermata e sottoscritta.

Giulio Giannini

IL DIRETTORE DI CANCELLERIA
(Giovanna Dionetto)



Giovanna Dionetto

APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da **GIOVANNA DIONETTO**

Agente in qualità di **DIRETTORE DI CANCELLERIA**

Tribunale Ordinario di Roma

È segnato dal contrassegno/timbro

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma

in data **- 9 GIU. 2005** e sotto il N. **1225/7** del Reg. delle Apostille

con sigillo dell'Ufficio legalizzazioni.

IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE

Dott. Ferdinando Correale

Ferdinando Correale



EXHIBIT 4

10/549958

JC17 Rec'd PCT/FTO 15 SEP 2005



EXHIBIT 4
24 SETTEMBRE 2003

Mod. 2101

MINISTERO DELLA SANITÀ

Istituto Superiore di Sanità

00161 Roma
VIALE REGINA ELENA, 299
TELEGRAMMI: ISTISAN-ROMA
TELEX: 06610071
TELEFAX: 0649387118

N. 45858/SA67

Risposta al Foglio del

N.

Allegati

Notarbartolo & Gervasi S.p.A.
Corso di Porta Vittoria n. 9
20122 MILANO

OGGETTO: domanda di brevetto internazionale n. PCT/EP02/04303 del 18.04.2002 dal titolo "Use of inhibitors of protease of the Human immunodeficiency virus (HIV) ..." - inventore: Dott.ssa Barbara Ensoli.

Con riferimento alla lettera dell'08.09.2003 si manifesta l'interesse al proseguimento

REDACTED

REDACTED

IL DIRETTORE DEGLI AFFARI AMMINISTRATIVI
E DELLE RISORSE ECONOMICHE
(Dott.ssa R. M. MARTOCCHIA)

REDACTED

NOTARBARTOLO & GERVASI MILANO	
RECEIVED	
25 SET. 2003	
LA	

REDACTED

REDACTED

Si prega di inviare per ogni lettera un solo esemplare e indicare nella riga di N. di protocollo o nei suoi riferimenti



10/549958

[EXHIBIT 4]
[Registered letter]

SET OF
FORMS
Health -278

Mod. 2101
00161 Rome, 24 SEPTEMBER 2003
Viale Regina Elena, 299
Telegrams: ISTISAN-ROMA
Telex: 06610071
Fax: 0649387118

[STAMP]
MINISTRY OF HEALTH
ISTITUTO SUPERIORE DI SANITA'
N.: 45858/SA67

JC17 Rec'd PCT/PTO 15 SEP 2005

Reply to Document of the:
N.:

Notarbartolo & Gervasi S.p.A.
Corso di Porta Vittoria n. 9
20122 MILAN

Enclosures:

RE: international patent application n. PCT/EP02/04303 of the 18.04.2002, title: "Use of inhibitors of protease of the Human immunodeficiency virus (HIV)..." -

Inventor: Doctor Barbara Ensoli

With reference to the letter of the 08.09.2003, the interest to proceed with the application mentioned in the subject is confirmed

REDACTED

REDACTED

THE DIRECTOR OF THE ADMINISTRATIVE AFFAIRS AND ECONOMIC RESOURCES
(Dr. R. M. MARTOCCIA)
[illegible signature]

2770PTWO 30.09.03
Call 155 to remind that we are waiting
for instructions concerning the
nationalisation to submit to Dr.
Cozzano. [...]

NOTARBARTOLO &
GERVASI
MILAN
RECEIVED
29 SEPT. 2003
[SIGNED]

TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

Addi1.2.106.2005..... avanti al sottoscritto Cancelliere è presente il

Signor: GIANNINI GIULIO.....

documento: PATENTE AUTO..... N. RM6089390M

rilasciato da MSIG-RM..... il 28.08.2002.....

Il quale chiede di asseverare con giuramento il suesposto atto. Io
Cancelliere, previa ammonizioni di legge, invito il comparente al
giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente
adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

[Handwritten signature]



A DESTINARE AL CANCELLIERE
INTELLIGIBILE
[Handwritten signature]

CRONOLOGICO

N. 3/8063.....

Roma 2.1.106.2005.

IL COLLABORATORE *[Handwritten signature]*

APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da MARIA ANTONIETTA FRANZINO

Agente in qualità di DIRETTORE di CANCELLERIA

È segnato dal contrassegno/libro Tribunale Ordinario di Roma

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma
in data 1.2 LUG. 2005 e sotto il N. 1510/7 del Reg. delle Apostille
con sigillo dell'Ufficio legalizzazioni.



IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE

Dott. Ferdinando Correale

A handwritten signature in black ink, appearing to be "F. Correale", written over a horizontal line.

[Faint, illegible text, possibly a date or reference number]



Istituto Superiore di Sanità



00161 Roma, 30 Settembre 2003

VIALE REGINA ELENA, 299
TELEGRAMMI: ISTISAN ROMA
TELEFONO: 06 49801
TELEFAX: 06 49387118
<http://www.iss.it>

Dott.ssa Rosa M. Martoccia
Dirigente dei Servizi Amministrativi
SEDE

Oggetto: Domanda di brevetto internazionale n. PCT/EP02/04303 del 18.04.2002
Inventore: Dr. Barbara Ensoli
Rif. N&G: 2770PTWO/cr

In riferimento alla comunicazione dell' 8/09/2003 della Società Notarbartolo & Gervasi S.p.A., e a Vostra lettera del 16 Settembre c.a. (prot. 44217/SA67), si ribadisce l'intenzione a proseguire con le fasi nazionali inerenti il brevetto in oggetto (scadenza 18/10/03), così come specificato nella ns. precedente lettera datata 12 Settembre 2003.

A tal fine, considerata l'urgenza e l'importanza di dare avvio ai procedimenti di nazionalizzazione si richiede ai competenti uffici amministrativi, sulla base dell'e-mail allegata, di provvedere alla richiesta di un preventivo analitico alla Notarbartolo & Gervasi S.p.A., avendo cura che nella sua formulazione siano riportate le seguenti specifiche:

- Numero totale pagine del brevetto
- Numero totale figure
- Lista dei costi, con suddivisione degli oneri per "tasse ufficiali" in: "costi traduzione per fase" e "tasse per fase".

Tale preventivo dovrebbe essere formulato facendo riferimento al prospetto dei paesi allegato alla comunicazione e-mail, al fine di estendere la protezione derivante dal deposito brevettuale ai paesi indicati e valutare gli oneri derivanti.

Dott.ssa Barbara Ensoli
Laboratorio di Virologia
SEDE



10/549958

MOD. 2200

JC17 Rec'd PCT/PTO 15 SEP 2005

ISS STAMP

MIN. OF HEALTH STAMP

00161 Rome, 30 September 2003
Viale Regina Elena 299
Telegram: ISTISAN ROMA
Telephone: 06 49801
Telex: 06 49387118
<http://www.iss.it>

Doctor Rosa M. Martoccia
Manager of Financial Services
MAIN OFFICE

Re: International patent application n. PCT/EP02/04303 of the 18.04.2002
Inventor: Dr. Barbara Ensoli
Ref. N&G: 2770PTWO/er

With reference to the letter of the 08/09/2003 of the Company "Notarbartolo & Gervasi S.p.A.", and to Your letter of the 16th of September of the current year (file 44217/SA67), we stress the intention to proceed with the national phases concerning the patent in hand (expiry 18/10/03), as specified in our previous letter of the 12th of September 2003.

In consideration of the urgency and importance to start the nationalisation procedures, the competent financial offices are requested to supply an analytical estimate to Notarbartolo & Gervasi S.p.A. including the following specifications:

- Total number of pages of the patent;
- Total number of figures;
- List of the costs, with the division of charges in "official taxation" in: "costs of translation per phase" and "taxes per phase".

Said estimate should be drafted according to the table of Countries enclosed to the e-mail in order to expand the protection deriving from the patent deposit to such countries in order to evaluate the charges that could arise.

[Illegible signature]
Doctor Barbara Ensoli
Virology Lab
MAIN OFFICE

TRIBUNALE DI ROMA

Ufficio di Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

Addi 09 GIU. 2005... avanti al sottoscritto Cancelliere è presente il

Signor: GIANNINI Giulio

documento: PA N. RM 608939

rilasciato da MCTC-RM il 28/08/2002

Il quale chiede di asseverare con giuramento il suesposto atto. Io
Cancelliere, previa ammonizioni di legge, invito il comparente al
giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente
adempiuto all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

Giulio Giannini

IL DIRETTORE DI CANCELLERIA
(Giovanna Dionette)



G. Dionette

APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da GIOVANNA DIONETTE

Agente in qualità di DIRETTORE DI CANCELLERIA
Tribunale Ordinario di Roma

È segnato dal contrassegno/timbro

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma

In data 9 GIU. 2005 e sotto il N. 1225/6 del Reg. delle Apostille

con sigillo dell'Ufficio legalizzazioni.



IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE
Dott. Ferdinando Correale

F. Correale

CRONOLOGICO

N. 6510

09 GIU. 2005

Roma,

IL COLLABORATORE

EXHIBIT 6

10 / 549958

JC17 Rec'd PCT/PTO 15 SEP 2005



Istituto Superiore di Sanità

N. 49602 / RE 67

Risposta al Foglio del

N.

Allegati

14 OTTOBRE 2003



00161 Roma,

VIALE REGINA ELENA, 298
TELEGRAMMI: IstitSan ROMA
TELEFONO: 06 49801
TELEFAX: 06 49387118
<http://www.iss.it>

Notarbartolo & Gervasi S.p.A.
Corso di Porta Vittoria n. 9
20122 MILANO

✓ e p.c. Dott.ssa Barbara Ensoli
Laboratorio di Virologia
Sede

OGGETTO:

domanda di brevetto internazionale n. PCT/EP02/04303 del 18.04.2002 dal titolo "Use of inhibitors of protease of the Human immunodeficiency virus (HIV) ..." - inventore: Dott.ssa Barbara Ensoli.
Vs. Rif. 2770PTWO/er

Con riferimento alla lettera dell'08.09.2003 e facendo seguito alla nostra nota Prot. n. 45858/SA67 in data 24.09.2003, relativamente ai procedimenti di nazionalizzazione, si chiede la trasmissione di un preventivo analitico suddiviso sulla base di quanto di seguito specificato:

- Numero totale pagine del brevetto;
- Numero totale figure
- Lista dei costi, con suddivisione degli oneri per tasse ufficiali in: "costi traduzione per fase" e "tasse per fase".

Il suddetto preventivo dovrà essere formulato con riferimento al prospetto dei Paesi che si allega alla presente.

**IL DIRETTORE DEGLI AFFARI AMMINISTRATIVI
E DELLE RISORSE ECONOMICHE**
(Dott.ssa R. M. MARTOCCIA)



10/549958

[STAMP]
ISTITUTO SUPERIORE DI SANITA'

00161 Rome, 14 October 2003
Viale Regina Elena, 299
Telegram: ISTISAN-ROMA
Telex: 06610071
Telephone: 0649387118
<http://www.iss.it>

JC17 Rec'd PCT/PTO 15 SEP 2005

Notarbartolo & Gervasi S.p.A
Corso di Porta Vittoria n. 9
20122 MILAN

N°: 49602/RE67
Reply to the File of the:
N°: [...]
Enclosures: [...]

and copy to:
DOCTOR BARBARA ENSOLI
VIROLOGY LAB
MAIN OFFICE

Re: International patent request n. PCT/EP02/04303, deposited on the 18.04.2002 "Use of inhibitors of protease of the Human immunodeficiency virus (HIV) ..". – inventor: Doctor Barbara Ensoli.

Your Ref. 2770TTWO/er

With reference to the letter of the 08.09.2003 and following our letter n. 45858/SA67 of the 24.09.2003, concerning the nationalisation procedures, You are kindly required to forward an analytical list of the foreseen expenses drafted according to the what is hereafter specified:

- Total number of pages of the patent;
- Total number of figures;
- List of expenses dividing the expenses relating to official taxation in: " costs of translation per phase" and "taxes per phase".

The aforementioned estimate must be drafted with reference to the table of Countries hereto enclosed.

THE DIRECTOR OF FINANCIAL AFFAIRS AND ECONOMIC RESOURCES
(Doctor R. M. MARTOCCIA)

[Illegible signature]

NALE DI ROMA

Atti Notori - Perizie e Traduzioni

CRONOLOGICO

N. 6510

09 GIU. 2005
Roma,

IL COLLABORATORE

VERBALE DI GIURAMENTO

Addi 09 GIU. 2005..... avanti al sottoscritto Cancelliere è presente il

Signor: GIANNINI Giulio

documento: P.A. N. RM 6089390 M

rilasciato da MGTc-RM il 28/08/2002

il quale chiede di asseverare con giuramento il suesposto atto. Io
Cancelliere, previa ammonizioni di legge, invito il comparente al
giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente
adempiuto all'incarico affidatomi a tale scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

Giulio Giannini

IL DIRETTORE DI CANCELLERIA
(Giovanna Dionette)



Giovanna Dionette

APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da GIOVANNA DIONETTE

Agente in qualità di DIRETTORE DI CANCELLERIA

È segnato dal contrassegno/timbro Tribunale Ordinario di Roma

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma
in data 9 GIU. 2005 e sotto il N. 1225/4 del Reg. delle Apostille
con sigillo dell'Ufficio legalizzazioni.



IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE
Dott. Ferdinando Correale

Ferdinando Correale

EXHIBIT 7

10/549958

JC17 Rec'd PCT/PTO 15 SEP 2005

JC17 Rec'd PCT/PTO 15 SEP 2005

30/10/2003

To: "Paola Sergiampietri" <sgpietri@iss.it>, "Dott.ssa Rosa Martoccia":dirghensa@iss.it, monica.nusca@iss.it;, BARBARA ENSOLI <ensoli@iss.it>
From: Cozzone Giovan Battista <cozzone@tin.it>
Subject: Re: PATENT PI (Rif. N&G: 2770PTWO/er)
Cc:
Bcc:

Sull'ultimo punto, suggerisco affidare la fase nazionale USA a Pennie & Edmunds.

Giovanni Cozzone

> -----Messaggio originale-----
> Da: Gerli Anna [mailto:a.gerli@ngpatent.it]
> Inviato: giovedì 30 ottobre 2003 15.43
> A: Barbara Ensoli
> Cc: Primiceri Maria Vittoria
> Oggetto: R: PATENT PI (Rif. N&G: 2770PTWO/er)
> Priorità: Alta
>
>
> Gentile Dr.a Sergiampietri,
> Con riferimento alla sua e-mail del 27 corr. desideriamo precisare quanto
> segue:
> 1) non abbiamo mai ricevuto da Voi alcuna lettera datata 30.9.2003 e
neppure
> successive comunicazioni
> 2) in data 20 ottobre abbiamo ricevuto da parte dei Vostri Uffici
> Amministrativi la lettera da Voi indicata con richiesta di un preventivo
più
> dettagliato
> 3) in data 23 ottobre via fax "Contratto di affidamento incarico" da parte
> dei Vostri Uffici Amministrativi
> ciò premesso ci siamo subito attivati per il deposito delle fasi nazionali
> nei Paesi cui Vostro elenco.
> A questo riguardo e con riferimento alla sua e-mail del 29-10-2003
> indirizzata alla Dr.a Primiceri facciamo presente quanto segue:
> 1) la domanda di Brevetto Europeo (con termine 31 mesi) verrà estesa
anche

> ai seguenti Paesi: Albania, Romania, Slovenia, Lituania, Lettonia, Macedonia

> per quanto riguarda Repubblica Ceca, Repubblica Slovacca, Bulgaria,

> Estonia ed Ungheria (con termine 31 mesi) abbiamo già passato istruzioni ai

> nostri

> corrispondenti di procedere

> 2) Della Convenzione OAPI fanno parte anche Guinea Bissau e Guinea Equatoriale (termine 30 mesi)

> 3) Della Convenzione ARIPO fanno parte anche Mozambico, Sierra Leone e Zambia (termine 31 mesi)

> 4) La Turchia fa parte della Convenzione Europea (termine 31 mesi)

> Per quanto riguarda infine la preparazione di un preventivo analitico Vi

> preghiamo di voler pazientare sino alla prossima settimana.

> Con l'occasione vorremmo altresì che ci precisaste se per il deposito in

> U.S.A. dovremo appoggiarci all'Ufficio Brevetti P&E, a cui è stata girata la

> gestione della Vostra precedente domanda (ns. rif. 1354PTUS). Vi facciamo

> presente che la questione riveste particolare urgenza in quanto il termine

> per gli U.S.A. è a 30 mesi con recupero mediante una Petition e pagamento di

> una sovrattassa.

> Cordiali saluti

>

>

> > -----Messaggio originale-----

> > Da: Barbara Ensoli [SMTP:ensoli@iss.it]

> > Inviato: lunedì 27 ottobre 2003 14.41

> > A: Ng-roma; Gerli Anna

> > Cc: Primiceri Maria Vittoria; Giovanni Cozzone

> > Oggetto: PATENT PI (Rif. N&G: 2770PTWO/er)

> > Priorità: Alta

> >

> > Oggetto: Domanda di brevetto internazionale n. PCT/EP02/04303 del

> 18.04.2002 -

> >

> > Inventore: Dr. Barbara Ensoli - Rif. N&G: 2770PTWO/er

> >

> >

> >

> >

> > Gent.le Dr. Gerli,

> >

> >

> >

> > Ad integrazione della ns. lettera del 30/9/2003 e a seguito delle

> intercorse comunicazioni, si ribadisce l' > > intenzione a proseguire con

le

- > fasi nazionali inerenti il brevetto in oggetto.
- > >
- > >
- > >
- > > A tal fine, considerata l'> 'urgenza e l'> 'importanza di proseguire con
- > procedimenti di nazionalizzazione, si notifica nuovamente la designazione di
- > tutti i paesi riportati nella lista inviata con nostra autorizzazione a
- > procedere del 30 Settembre c.a. (e lettera dei competenti uffici
- > amministrativi del 14/10/2003, Prot. N. 49602/RE67).
- > >
- > >
- > >
- > > Si richiede con urgenza alla N&G SpA l'> 'indicazione dei costi
- > sostenibili per l'> 'estensione alle fasi nazionali nei sottoelencati paesi
- > (attualmente non contemplati nel prospetto della N&G inviatoci il 22
- > Settembre 2003):
- > >
- > >
- > >
- > > EP: Albania, Repubblica Ceca, Repubblica Slovacca, Romania, Slovenia,
- > Bulgaria, Estonia, Ungheria, Latvia, Lituania, Macedonia
- > >
- > > OAPI: Guinea Equatoriale, Guinea Bissau
- > >
- > > ARIPO: Mozambico, Sierra Leone, Zambia
- > >
- > > Altri: Turchia
- > >
- > >
- > >
- > > Si richiede gentilmente conferma della loro effettiva appartenenza ai
- > gruppi specificati nella lista da noi preventivamente inviata alla Vs.
- > attenzione
- > >
- > >
- > >
- > > In seconda istanza restiamo in attesa di un preventivo analitico avendo
- > cura che nella sua formulazione siano riportate le seguenti specifiche:
- > >
- > >
- > >
- > > - Numero totale pagine del brevetto
- > >
- > > - Numero totale figure

> >
 > > - Lista dei costi, con suddivisione degli oneri per > "> tasse
 > ufficiali> "> in: > "> costi traduzione per fase> "> e > "> tasse per
 > fase> "> .
 > >
 > >
 > >
 > > Tale preventivo dovrebbe essere formulato facendo riferimento al
 prospetto
 > dei paesi precedentemente da noi trasmesso e nuovamente alleato alla
 > presente. In merito ai punti sopraelencati giungerà, alla Sua attenzione,
 > ulteriore comunicazione dei competenti uffici amministrativi.
 > >
 > >
 > >
 > > In attesa di riscontro
 > >
 > >
 > >
 > > Cordiali saluti
 > >
 > >
 > >
 > >
 > >
 > >
 > > Sergiampietri Paola
 > >
 > > Segreteria
 > >
 > >
 > >
 > >
 > >
 > > Dr. Barbara Ensoli
 > >
 > > Laboratorio di Virologia
 > >
 > > Istituto Superiore di Sanità
 > >
 > > V.le Regina Elena, 299
 > >
 > > 000161 Roma
 > >
 > > Tel: +39-06-49903209
 > >
 > > Fax: +39-06-49903002

> >
> > E-mail: ensoli@iss.it <mailto:ensoli@iss.it>
> > << File: Fasi.naz.PI_EP02=04303.xls >>
>

--

Best Regards

Sincerely,

Giovanni Cozzone, CEO
<http://www.help-finance.com>
by BEI Srl.
Via Montopoli, 4
00199, Roma

Tel: ++39.347.782.9440
Fax: +39.06.233.231.988
Email: vcnet@help-finance.com

6/11/2003

To: "Rossetti Elisa" <e.rossetti@ngpatent.it>
From: Cozzone Giovan Battista <cozzone@tin.it>
Subject: Re: I: PATENT PI (Rif. N&G: 2770PTWO/er)
Cc: "Dott.ssa Rosa Martoccia":dirghensa@iss.it, monica.nusca@iss.it;; BARBARA ENSOLI <ensoli@iss.it>, Paola Sergiampietri <sgpietri@iss.it>
Bcc:

gentile Dott.ssa

Ho già informato ISS che ritengo opportuno utilizzare Pennie & Edmunds anche per questo caso e credo che riceverete comunicazione a tal fine dall'Amministrazione oggi.

Cordiali Saluti

Giovanni Cozzone
Advisor del CdA in materia di strategia e gestione
delle attività brevettuali e Technology Transfer
ISTITUTO SUPERIORE DI SANITA'
Tel: +39 347 782 9440
Fax: +39 06 233 231 988

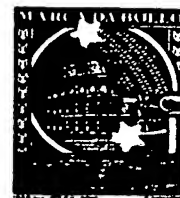
Facendo seguito al precedente messaggio, Vi rammentiamo che siamo ancora in attesa di conoscere il nominativo dell'agente USA al quale spedire l'incarico per la fase nazionale del suddetto caso.

Cordiali saluti

**Elisa Rossetti
NOTARBARTOLO & GERVASI
Corso di Porta Vittoria, 9
20122 Milan (Italy)**

**tel. +39 025417991
fax +39 0254179920
mailto:notage@ngpatent.it
mailto:e.rossetti@ngpatent.it**

10549958
JC17 Rec'd PCT/PTO 15 SEP 2005



30/10/2003

in file
To: "Paola Sergiampietri" <sgpietri@iss.it>, "Dott.ssa
Rosa Martoccia": dirghensa@iss.it,
monica.nusca@iss.it;, BARBARA ENSOLI
<ensoli@iss.it>

From: Cozzone Giovan Battista <cozzone@tin.it>

Subject: Re: PATENT PI (Rif. N&G: 2770PTWO/er)

Cc:

Bcc:

As far as the last point is concerned, my advise is to
entrust the U.S.A. national phase to Pennie &
Edmunds.

Giovanni Cozzone

[ORIGINAL MESSAGE]

From: Gerli Anna [mailto:a.gerli@ngpatent.it]

Sent: Thursday 30th of October 2003 15.43

To: Barbara Ensoli

Cc: Primiceri Maria Vittoria

Object: R: PATENT PI (Ref. N&G: 2770PTWOO/er)

Priority: High

Dear Doctor Sergiampietri,

with reference to Your e-mail of the 27th of this
month, we wish to define precisely the following
details:

- note*
- 1) we never received any letter dated 30/09/2003 from You, nor any following communications;
 - 2) on the 20th of October we received the letter You indicated with the request of a more detailed estimate from Your Administrative Office;
 - 3) we received on the 23rd of October, via fax, the "Commission assignment contract" from Your Administrative Office; that being stated, we immediately began to work on the deposit for the national phases in the Countries You included in Your list.

In this respect and with reference to Your e-mail of the 29-10-2003 addressed to Doctor Primiceri, we remind the following:

- 1) the European Patent application (with expiry within 31 months) will be extended also to the following Countries: Albania, Rumania, Slovenia, Lithuania, Latvia, Macedonia; as far as the Czech Republic, the Slovenian Republic, Bulgaria, Estonia and Hungary are concerned, (with expiry within 31 months) we already instructed our correspondents to proceed;
- 2) also Guinea Bissau and Equatorial Guinea belong to the OAPI Convention (expiry within 30 months);
- 3) also Mozambique, Sierra Leon and Zambia belong

brw&ie

to the ARIPO Convention (expiry 31 months);

- 4) Turkey is not part of the European Convention (expiry 31 months).

And finally, as far as the drafting of an analytical estimate is concerned, we beg You to wait until next week.

We seize the opportunity to ask You to specify if we must rely on P&E's Patent Office for the deposit in the U.S.A., to whom You transferred the management of Your previous application (our ref. 1345PTUS).

We remind You that this subject is extremely urgent because the expiry for the U.S.A. is of 30 months with a recovery through Petition and the payment of an additional tax.

Yours sincerely.

[ORIGINAL MESSAGE]

From: Barbara Ensoli

Sent: Monday, 27th of October 2003 14.41

To: Ng-roma; Gerli Anna

Cc: Primiceri Maria Vittoria; Giovanni Cozzone

Object: PATENT PI (Ref. N&G: 2770PTWOO/er)

Priority: High

Object: International patent application n.

PCT/EP02/04303 of the 18/04/2002

Inventor: Doctor Barbara Ensoli - Ref. N&G:
2770PTWO/er

Dear Doctor Gerli,

As an integration to our letter of the 30/09/2003 and following the communications exchanged, we confirm our intention to proceed with the national phases concerning the patent in question.

In this order, keeping in due consideration the urgency and the importance to pursue the nationalisation procedures, we deem it necessary to notify again the designation of all the countries reported in the list sent together with our authorisation to proceed of the 30th of September of this year (and also the letter of the competent Administrative Office of the 14/10/2003, Reg. N. 49602/RE67).

N&G S.p.A. is urgently required to notify the costs expected for the extension of the national phases in the following countries (at present they are not included in N&G's report sent on the 22nd of September 2003).

EP: Albania, Czech Republic, Slovak Republic, Rumania, Slovenia, Bulgaria, Estonia, Hungary, Latvia, Lithuania, Macedonia;



to be

OAPI: Equatorial Guinea, Guinea Bissau;
ARIPO: Mozambique, Sierra Leon, Zambia;
Others: Turkey.

You are kindly requested to confirm their effective belonging to the groups specified in the list that we sent in advance to Your attention.

We also await an analytical estimate in which you must include the following specifications:

- total number of pages constituting the patent;
- total number of figures;
- list of costs, with the division of the costs in "official taxes" in: "translation costs per phase" and "phase costs".

This estimate should be formulated with reference to the report to the report of the countries that we sent previously and enclosed again herein.

As to the aforementioned points, the competent administrative office will send to Your attention further communications.

Awaiting Your kind reply,

Yours sincerely.

Sergimpietri Paola

SECRETARY

Doctor Barbara Ensoli

Laboratory of Virology


Istituto Superiore di Sanità

V.la Regina Elena, 299

00161 ROMA

Tel.: + 39-06-49903209

Fax: + 39-06-49903002

E-mail: ensoli@iss.it [mailto:ensoli@iss.it]

File: Nat. Phases PI_EP02=04303.xls

Best regards

Sincerely,

Giovanni Cozzone, CEO

<http://www.help-finance.com>

by BEI Srl.

Via Montopoli, 4

00199, Rome

Tel.: + 39.347.782.9440

Fax: + 39.06.233.231.988

Email: vcnet@help-finance.com

6/11/2003

To: "Rossetti Elisa" <e.rossetti@ngpatent.it>

From: Cozzone Giovan Battista <cozzone@tin.it>

**Subject: Re: I: PATENT PI (Rif. N&G:
2770PTWO/er)**

**Cc: "Dott.ssa Rosa Martoccia":dirgensa@iss.it,
monica.nusca@iss.it;; BARBARA ENSOLI**

En. 1
<ensoli@iss.it>, Paola Sergiampietri

<sgpietri@iss.it>

Bcc:

Dear Doctor,

I have already informed ISS that I deem the use of Pennie & Edmunds appropriate even in this case and I think that you will receive the communication concerning this subject from the Management today.

Yours sincerely

Giovanni Cozzone

Advisor of the Board of Directors of strategy and management of the patent activities and Technology Transfer

ISTITUTO SUPERIORE DI SANITA'

Tel: +39 347 782 9440

Fax: +39 06 233 231 988

Following the previous message, we remind You that we are still awaiting the name of the agent in the U.S.A. to whom we must send the commission of the national phase of the aforementioned case.

Yours sincerely.

Elisa Rossetti

NOTARBARTOLO & GERVASI

Corso di Porta Vittoria, 9-20122 Milan (Italy)

Tel.: + 39.025417991-Fax: + 39. 02541179920

mailto: notage@ngpatent.it

mailto: e.rossetti@ngpatent.it

TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

Addi12 MAG 2005... avanti al sottoscritto Cancelliere è presente il

Signor: GIANNINI GIULIO.....

documento: PATENTE AUTO..... N. RM.6089390M

rilasciato da: MCTC-RM..... il 28.08.2002...

Il quale chiede di asseverare con giuramento il suesposto atto. Io
Cancelliere, previa ammonizioni di legge, invito il comparente al
giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente
adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

Firma Cancelliere

IL FUNZIONARIO DI CANCELLERIA
Dott. Vito Landolfi



CRONOLOGICO

5297

N.**12 MAG 2005**.....

Roma,

IL COLLABORATORE

EXHIBIT 8

10/549958
JC17 Rec'd PCT/PTO 15 SEP 2005



Istituto Superiore di Sanità



00161 Roma, 31 OTT. 2003

VIALE REGINA ELENA, 299
TELEGRAMMI: ISTISAN ROMA
TELEFONO: 06 49801
TELEFAX: 06 49387118
<http://www.iss.it>

Dott.ssa Rosa M. Martoccia
Dirigente dei Servizi
Amministrativi
SEDE

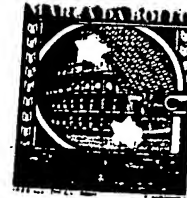
Oggetto: Domanda di brevetto internazionale n. PCT/EP02/04303 del 18.04.2002 -
Inventore: Dr. Barbara Ensoli - Rif. N&G: 2770PTWO/er

In riferimento alla comunicazione e-mail pervenutaci dalla Dr. Gerli (Notarbartolo & Gervasi S.p.A), in data 30/10/2003, si manifesta l'urgenza e l'interesse al proseguimento di tale domanda e si comunica che, per quanto concerne il deposito negli Stati Uniti, la gestione del brevetto in oggetto dovrà essere affidata allo studio Pennie & Edmonds LLP (già incaricato della fase nazionale USA della ns. precedente domanda di brevetto, rif. N&G: 1354PTUS).

Si richiede pertanto ai competenti uffici amministrativi di provvedere alla relativa comunicazione alla Notarbartolo&Gervasi SpA.

Cordiali saluti

Dott.ssa Barbara Ensoli
Laboratorio di Virologia
SEDE



ISTITUTO SUPERIORE DI SANITA'

00161 ROME, 31ST OF OCTOBER 2003

VIALE REGINA ELENA, 288

TELEGRAMS: ISTISAN ROMA

TELEPHONE: 06 48801

FAX: 06 48387118

<http://www.iss.it>

Doctor Rosa M. Martoccia

Director of the Administration Services.

HEAD OFFICE

Object: International patent application n. PCT/EP02/04303 of the 18.04.2002 – Inventor: Doctor Barbara Ensoli - Ref. N&G: 2770PTWO/er.

With reference to the e-mail received from Doctor Gerli (Notarbartolo & Gervasi S.p.a.) on the 30.10.2003, we express the urgency and interest to pursue this application and we also notify that, as far as the deposit in the United States is concerned, the management of the patent in question must be entrusted to Pennie & Edmonds LLP Office (to whom the U.S.A national phase was already entrusted to in our previous patent application, ref. N&G: 1354PTUS).

The competent administrative office is therefore required to supply the respective communication to

ISS STAMP

STAMP

Notarbartolo & Gervasi S.p.A.

Yours sincerely.

[SIGNATURE]

Doctor Barbara Ensoli

Laboratory of Virology

HEAD OFFICE

TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

Addi ..21/03/2005..... avanti al sottoscritto Cancelliere è presente il

Signor: ..DANILO GIANNINI.....

documento: ..CARTA D'IDENTITÀ..... N. AK...8743070.

rilasciato da ..CONVUL DI ROMA..... il ..29/01/2005.....

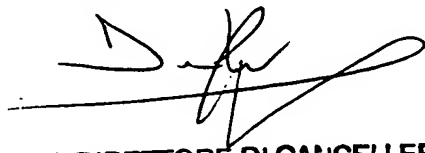
il quale chiede di asseverare con giuramento il suesposto atto. Io

Cancelliere, preve ammonizioni di legge, invito il comparsa al

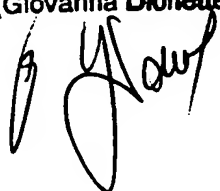
giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente

adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.



IL DIRETTORE DI CANCELLERIA
(Giovanna Dionette)

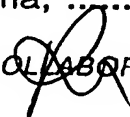


CRONOLOGICO

N. 2/ 3155

Roma, 21 MAR. 2005

IL COLLABORATORE



APOSTILLE

Convention de la Haye du 5 octobre 1961

RÉPUBLICA ITALIANA

Il presente atto è stato sottoscritto da GIOVANNA MONETTI

Agente in qualità di DIRETTORE DI CANCELLERIA

È segnato dal contrassegno/titolo Tribunale Ordinario di Roma

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma

In data 21 MAR. 2005 e sotto il N. 592/4 del Reg. delle Apostille

con sigillo dell'Ufficio legalizzazioni.



IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE
Dott. Ferdinando Correale

EXHIBIT 9

10/549958

JC17 Rec'd PCT/PTO 15 SEP 2005

JC17 Rec' ST/PTO 15 SEP 2005



"Stefania Ceccarelli"
<stefania.ceccarelli@iss.it>

03/04/2005 10:55 AM

To "Margaret B Brivanlou" <mbbrivanlou@jonesday.com>

cc "Adriane M Antler" <amantler@jonesday.com>,
<cozzone@tin.it>, "Ann W Chen"
<AWChen@jonesday.com>

bcc

Subject R: Dr. Ensoli's patent applications (our ref: 11340-008-999)

History: This message has been forwarded

Dear Dr Brivanlou,

thank you for your e-mail concerning Dr Ensoli's Patent Report.

We will let you know our instructions soon.

With reference to the US application in connection with the International Application No. PCT/EP02/04303, we are trying to understand what happened.

In fact it seems that in 2003 we started internal procedures to assignee to Pennie & Edmonds the US filing. Anyway, we will let you know the results of our research.

In the case there was some misunderstanding, are we still in time to file the US application, even paying for an additional fee if necessary?

Please, let us know.

Best regards

Stefania Ceccarelli

-----Messaggio originale-----

Da: Ann W Chen [mailto:AWChen@jonesday.com]

10/549958
JC17 PCT/PTO 15 SEP 2005

Inviato: martedì 1 marzo 2005 23.25

A: cozzone@tin.it

Cc: stefania.ceccarelli@iss.it; Adriane M Antler; Margaret B Brivanlou

Oggetto: Re: Dr. Ensoli's patent applications (our ref: 11340-008-999)

Please see attached.

=====




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=====

● 10 / 549958

● **EXHIBIT 10**

JC17 Rec'd PCT/PTO 15 SEP 2005



Margaret B
Brivanlou/JonesDay
Extension 7-3876
212-326-3876 (external)
03/10/2005 04:39 PM

To cozzone@tin.it
cc "Stefania Ceccarelli" <stefania.ceccarelli@iss.it>,
amantier@JonesDay.com, awchen@jonesday.com
bcc
Subject U.S. National Stage of PCT/EP02/04303 (our ref.
11340-007-999)

Dear Giovanni:

Further to our discussion last week, we have reviewed our files in connection with the above -identified matter and we have no correspondence, until the files were transferred to us recently, either ISS or Notarbartolo & Gervasi regarding the filing of a U.S. national stage application for PCT/EP02/04303.

REDACTED

REDACTED

Best wishes,
Peg

Margaret B. Brivanlou, Ph.D.
Jones Day
222 East 41st Street
New York, New York 10017
212-326-3876 (phone)
212-755-7306 (fax)
MBBrivanlou@jonesday.com

=====

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=====

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:
Ensoli

Attorney Docket No.:
11340-007-999

International (PCT) Application No.:
PCT/EP02/04303

Filed:
April 18, 2002

Title:
USE OF HIV-PROTEASE INHIBITORS
TO BLOCK CELL MIGRATION AND/OR
INVASION, TISSUE INFILTRATION
AND OEDEMA FORMATION

DECLARATION OF DR. GIOVAN BATTISTA COZZONE

Attention: PCT Legal Staff
Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

GIOVAN BATTISTA COZZONE declares and states that:

1. I presently hold the position of the Board Advisor for Intellectual Property & Technology at the Istituto Superiore di Sanità (hereinafter "ISS"), the Assignee of the entire right, title and interest in the above-identified international patent application, No. PCT/EP02/04303 (hereinafter "the International Application"), by virtue of Italian national law R.D. 29 giugno 1939, n.1127, which was in existence at the time of filing Italian Patent Application No. RM2001A000210, to which the International Application claims priority. Specifically, Italian national law R.D. 29 giugno 1939, n.1127 mandates that ownership of inventions made by an employee, *i.e.*, Dr. Barbara Ensoli (inventor of the International Application), during employment by execution of an employment contract belongs to the employer, *i.e.*, ISS. ISS is also the Assignee of the entire right, title and interest in the U.S. national stage of International Application by virtue of an assignment from Dr. Ensoli. A copy of the assignment is enclosed herewith as Exhibit A.

2. By virtue of a consultancy contract with the President of ISS entered into in July of 2002, since that time I am responsible for coordinating the filing of the national stage applications of the International Application with the Italian law firm of Notarbartolo & Gervasi (hereinafter "N&G"). I provide this Declaration to explain the mistake in fact that led to the unintentional failure to file the U.S. national stage of the International Application by the relevant deadline.

3. On September 8, 2003, I was copied on an e-mail from Ms. Elisa Rossetti (an attorney at N&G) to Dr. Ensoli (the inventor), in which a copy of a letter dated September 8, 2003 from Ms. Maria Vittoria Primiceri (another attorney at N&G) to Dr. Rosa Martoccia (Director General of Administrative Services and Financial Affairs, which the ISS office that handles patent matters ("ISS Patent Office") is part thereof) was attached. In her letter dated September 8, 2003, Ms. Primiceri enclosed a copy of the International Preliminary Examination Report ("IPER") issued on July 29, 2003 for the International Application. In her letter, Ms. Primiceri reminded Dr. Martoccia that the last date to enter the national phase in the countries of interest would expire on October 18, 2003 and requested that instructions for national phase entry be provided to N&G by September 15, 2003. Copies of Ms. Primiceri's letter dated September 8, 2003 and the certified English translation thereof are attached hereto as Exhibit B. Exhibit B has been redacted to delete information not related to this Declaration.

4. On September 15, 2003, I replied to Ms. Rossetti's e-mail dated September 8, 2003. In my e-mail, in which I also addressed Ms. Primiceri of N&G and copied Dr. Ensoli (the inventor), Dr. Martoccia, Dr. Paola Sergiampietri (Dr. Ensoli's secretary) and Dr. Paolo Monini (a scientist who works in Dr. Ensoli's lab), all of ISS, I informed Ms. Rossetti that I planned to discuss the International Application with Dr. Ensoli and others who are involved with the International Application and would provide instructions to N&G on national phase entry before September 25, 2003. Copies of Ms. Rossetti's e-mail dated September 8, 2003 and my reply e-mail dated September 15, 2003 and their respective certified English translations thereof are attached hereto as Exhibit C.

5. In order to facilitate a discussion with the inventor and others involved with the International Application regarding in which countries to enter national phase, I telephoned the attorneys at N&G on September 19, 2003 and requested that cost estimates for

filing national stage applications of the International Application be provided to the ISS Patent Office.

6. On September 22, 2003, I received an e-mail from Ms. Rossetti (of N&G), copying Dr. Ensoli (the inventor), which enclosed a copy of a letter dated September 22, 2003 from Ms. Gerli (of N&G) to Dr. Martoccia. In her letter dated September 22, 2003, Ms. Gerli provided cost estimates for entering the national phase in countries including, *inter alia*, the United States, and requested that instructions to enter national phases be provided by September 25, 2003. Copies of Ms. Rossetti's e-mail dated September 22, 2003, and its attachment (*i.e.*, Ms. Gerli's letter dated September 22, 2003), and their respective certified English translation thereof are attached hereto as Exhibit D. Exhibit D has been redacted to delete information not related to this Declaration.

7. On September 23, 2003, Dr. Ensoli and others who are involved with the International Application and I discussed the International Application and agreed that ISS should proceed with the national stage applications.

8. On September 30, 2003, I wrote another e-mail to Ms. Rossetti (of N&G), copying Dr. Ensoli (the inventor), Ms. Primiceri (of N&G), and Dr. Martoccia and asked for a more detailed breakdown of the costs for filing the national stage applications of the International Application. Copies of my e-mail dated September 30, 2003 and the certified English translation thereof are attached hereto as Exhibit E.

9. On the same day, September 30, 2003, Ms. Gerli informed me in an e-mail that the detailed cost breakdown could not be provided before the October 18, 2003 deadline. Copies of Ms. Gerli's e-mail dated September 30, 2003 and the certified English translation thereof are attached hereto as Exhibit F.

10. On October 1, 2003, I informed Ms. Gerli in an e-mail, copying Dr. Martoccia and Dr. Ensoli (the inventor) that it was not indispensable to have the detailed cost breakdown by the October 18, 2003 deadline because that information was not necessary for ISS to determine whether to file national stage applications of the International Application. Copies of my e-mail dated October 1, 2003 and the certified English translation thereof are attached hereto as Exhibit G.

11. In the meantime, I asked Dr. Ensoli (the inventor) to provide instructions to the ISS Patent Office regarding in which countries the national phase of the International Application was to be entered.

12. On October 27, 2003, I was copied on an e-mail from Ms. Sergiampietri (Dr. Ensoli's secretary) on behalf of Dr. Ensoli to Ms. Gerli (of N&G), which Dr. Ensoli confirmed her intention to proceed with the filing of national stage applications in connection with the International Application and to provide cost estimates for entering the national phase in certain designated countries not already included in Ms. Gerli's letter dated September 22, 2003 (see page 4, lines 6-8 of the certified English translation in Exhibit H).

13. In an e-mail dated October 30, 2003, I advised Dr. Martoccia, Ms. Sergiampietri and Dr. Ensoli that the U.S. law firm of Pennie & Edmonds LLP (hereinafter "P&E") should be entrusted with the U.S. national stage of the International Application (see page 1, lines 9-12 of the certified English translation in Exhibit H). This was in response to Ms. Gerli's e-mail dated October 30, 2003 in which she asked if N&G should rely on P&E to file the U.S. national stage application (see page 3, lines 7-11 of the certified English translation in Exhibit H). Thus, this e-mail was meant to inform Dr. Martoccia that ISS should instruct N&G to request P&E to file the U.S. national stage application.

14. In fact, in an e-mail dated November 6, 2003, I instructed Ms. Rossetti (of N&G) that the filing of the U.S. national stage of the International Application should be entrusted to P&E and indicated that the ISS Patent Office would be sending N&G instructions to that effect later in the day (see page 7, lines 5-8 of the certified English translation in Exhibit H).

15. Contrary to what I believed to have communicated to Dr. Martoccia, the ISS Patent Office did not ask N&G to instruct P&E to file the U.S. national stage application. Instead, in a letter dated November 6, 2003, Dr. Martoccia asked N&G to file the national stage applications in all the designated countries except in the U.S. and informed N&G that ISS would directly instruct P&E to file the U.S. national stage of the International Application. Copies of Dr. Martoccia's letter dated November 6, 2003 and the certified English translation thereof are attached hereto as Exhibit I. I was not copied on Dr. Martoccia's letter of instructions to N&G.

16. It is clear that the ISS Patent Office misunderstood my instructions. As a result, Dr. Martoccia issued inadvertently mistaken instructions regarding the U.S. national stage application to N&G and, as a result, N&G did not instruct P&E to file the U.S. national stage of the International Application. I also did not instruct P&E to file the U.S. national stage application under the assumption that, pursuant to my e-mail dated November 6, 2005, the ISS Patent Office would instruct N&G to instruct P&E to file the U.S. national stage application.

17. The failure to file the U.S. national stage of the International Application was not recognized until after I had instructed the U.S. law firm of Jones Day (hereinafter "JD") to take over the files of the national stage applications of the International Application in December of 2004, and after the attorneys at JD had had a chance to review the files of the national stage applications by March of 2005.

18. I was alerted by JD of the potential omission to enter the U.S. national stage in a letter dated March 1, 2005 from Dr. Margaret Brivanlou (an attorney currently at JD and previously at P&E prior to January 1, 2004). Subsequently, upon investigation, I confirmed to JD in an e-mail dated March 28, 2005 from me to Dr. Adriane Antler (also an attorney currently at JD and previously at P&E prior to January 1, 2004) that this omission had indeed occurred, and I authorized the attorneys at JD to begin preparing a petition to revive the abandoned U.S. national stage of the International Application. Copies of Dr. Brivanlou's letter dated March 1, 2005 and my e-mail dated March 28, 2005 are attached hereto as Exhibits J and K, respectively. Exhibits J and K have been redacted to delete information not related to this Declaration.

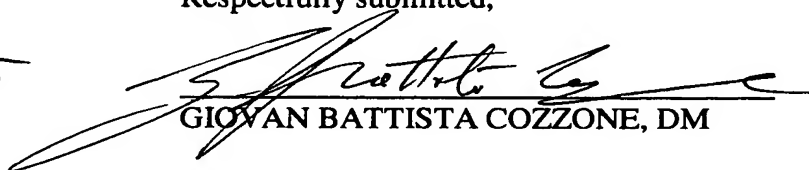
19. In view of the foregoing, I submit that through inadvertent error based on a mistake in fact, the U.S. national stage of the International Application was not timely filed by thirty months from the claimed priority date, *i.e.*, October 18, 2003. I further submit that the entire delay in filing the U.S. national stage of the International Application until the filing of a grantable petition under 37 C.F.R. § 1.137(b) was unintentional. Once I became aware of the omission in filing the U.S. national stage application, I further investigated and assisted in collecting documents that evidence ISS's intention to timely file the U.S. national stage of the International Application, and provided such documents to JD for preparation of the accompanying Petition.

20. I declare further that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the U.S. national stage application of the above-identified international patent application or any patents issuing on the U.S. national stage application.

Respectfully submitted,

Date:

Aug. 31, 2005


GIOVAN BATTISTA COZZONE, DM

10/549958

JC17 Rec'd PCT/PTO. 15 SEP 2005

EXHIBIT A

SOLE

ASSIGNMENT

WHEREAS, I, BARBARA ENSOLI, ASSIGNOR, citizen of Italy, residing at Via Capo Sottile, 25, 00139, Rome, Italy, am the inventor of the invention in USE OF INHIBITORS OF THE PROTEASE OF THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) TO BLOCK CELL MIGRATION AND/OR INVASION, TISSUE INFILTRATION AND OEDEMA FOR THE THERAPY OF DISEASES ASSOCIATED THEREWITH for which I have executed an application for a Patent of the United States

- ☒ which is executed on ☒ even date herewith or
☒ which is identified by Jones Day docket no. 11340-007-999
☒ which is the U.S. national stage of International Patent Application No. PCT/EP02/04303, filed April 18, 2002
☐ which was filed on , Application No.
☒ I hereby authorize and request my attorney(s), Adriane M. Antler or Margaret B. Brivanlou, at Jones Day, 222 East 41st Street, New York, New York 10017, to insert here in parentheses (Application number _____ filed _____) the filing date and application number of said application when known.

and WHEREAS, ISTITUTO SUPERIORE DI SANITÀ, ASSIGNEE, a corporation having an address at 299 Viale Regina Elena, 00161 Rome, Italy, is desirous of obtaining my entire right, title and interest in, to and under the said invention and the said application:

NOW, THEREFORE, in consideration of the sum of One Dollar (\$1.00) to me in hand paid, and other good and valuable consideration, the receipt of which is hereby acknowledged, I, the said ASSIGNOR, have sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over, unto the said ASSIGNEE, its successors, legal representatives and assigns, my entire right, title and interest in, to and under the said invention, and the said United States application and all divisions, renewals and continuations thereof, and all Patents of the United States which may be granted thereon and all reissues and extensions thereof; and all applications for industrial property protection, including, without limitation, all applications for patents, utility models, and designs which may hereafter be filed for said invention in any country or countries foreign to the United States, together with the right to file such applications and the right to claim for the same the priority rights derived from said United States application under the Patent Laws of the United States, the International Convention for the Protection of Industrial Property, or any other international agreement or the domestic laws of the country in which any such application is filed, as may be applicable; and all forms of industrial property protection, including, without limitation, patents, utility models, inventors' certificates and designs which may be granted for said invention in any country or countries foreign to the United States and all extensions, renewals and reissues thereof;

AND I HEREBY authorize and request the Commissioner for Patents and any Official of any country or countries foreign to the United States, whose duty it is to issue patents or other evidence or forms of industrial property protection on applications as aforesaid, to issue the same to the said ASSIGNEE, its successors, legal representatives and assigns, in accordance with the terms of this instrument.

AND I HEREBY covenant and agree that I have full right to convey the entire interest herein assigned, and that I have not executed, and will not execute, any agreement in conflict herewith.

AND I HEREBY further covenant and agree that I will communicate to the said ASSIGNEE, its successors, legal representatives and assigns, any facts known to me respecting said invention, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing, reissue and foreign applications, make all rightful oaths, and generally do everything possible to aid the said ASSIGNEE, its successors, legal representatives and assigns, to obtain and enforce proper protection for said invention in all countries.

IN TESTIMONY WHEREOF, I hereunto set my hand and seal this Sept 6 day of Sept 6, 2005.

Barbara Ensoli L.S.

Witnessed:

Sept 6, 2005
Date

STEFANIA CECCARELLI
Printed Name

Stefania Ceccarelli L.S.

Sept 6, 2005
Date

ANNAMARIA CARINCI
Printed Name

Annamaria Carinci L.S.

10/549958

JC17 Rec'd PCT/PTO 15 SEP 2005

EXHIBIT B



NOTARBARTOLO & GERVASI



Dr. G. Gervasi
Dr. D. Pallini Gervasi
Dr. A. Pallini Gervasi

Dr. G. Zucchini
Dr. L. Piccolo
Dr. G. Moretti
Dr. R. Janssen
Dr. M. V. Primiceri
Dr. L. Baldicci
Dr. G. Mariani
Dr. P. Gatti
Dr. P. Gatti
Dr. C. Acosta
Dr. G. Pallini
Dr. L. Pallini
Dr. S. Brazzini

Dr. S. Poncemi
Dr. S. Lorenz
Dr. S. Merli
Ing. B. Cinquanti
Ing. M. Donato

Dr. E. Maud
Dr. M. L. Quochi
Dipl. Chem. N. Weisgerber
Ing. G. Chiodi
Dr. R. Garza
Dr. E. Sarti
Dr. F. Gervasi
Dr. E. Fano
Ing. P. De Anna
Dr. M. Antonini
Dr. P. Gervasi
Dr. F. Chiodi

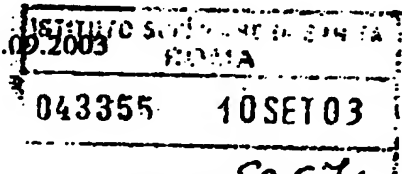
Ing. M. Savi
Dr. R. Russo
Dr. L. Ghislini
Dr. R. Appoloni
Ing. C. Borsani

Dr. E. Quastella
Dr. R. Mariani
Dr. L. Vasco
Dr. P. Fub
Ing. D. Dall'Asta

Avv. L. Iacocca
Avv. P. Sordani
Avv. M. Cammelli
Avv. P. Stancati
Dr. J. Gaudet

Spett.
ISTITUTO SUPERIORE DI SANITA'
Servizi Amministrativi
Divisione VIII - Contratti
c.a. Dr.ssa Martocchia
Viale Regina Elena 299
00161 ROMA

Milano, 08.09.2003



Oggetto: Domanda di Brevetto Internazionale N. PC1/EP02/04303
depositata il 18.04.2002

a nome ISTITUTO SUPERIORE DI SANITA'

dal titolo: "Use of inhibitors of protease of the human immunodeficiency virus (HIV)..."

Inventore: Barbara ENSOLI

Ns. rif. 2770PTWO/er

Con riferimento alla domanda in oggetto, Vi trasmettiamo copia dell'International Preliminary Examination Report emesso in data 29.07.2003.

REDACTED

REDACTED

REDACTED

20130 Milano Italy
80030 Munich Germany
60000 Lugano Switzerland
50120 Firenze Italy
00198 Roma Italy
35137 Padova Italy
10120 Torino Italy

Corso di Porta Venezia, 9
Riviera 21
via Besso, 9
Lungarno A. Vesputi, 24
Via Savola, 82
Lungo Riva, 10
Corso Ito Umberto, 9

Telephone
+39 02 5417000
+49 89 5170163
+41 091 9564230
+39 055 284417-264465
+39 06 8841688-8330618
+39 049 8704447
+39 011 4417733-4415545

Fax
+39 02 54170030
+49 89 51701650
+41 091 9564231
+39 055 280002
+39 06 8841687
+39 049 8704448
+39 011 8870000

E-mail
notary@ingpatent.it
mail@ingpatent.it
ingpatent@tin.it
notary@ingpatent.it
notary@ingpatent.it
notary@ingpatent.it
notary@ingpatent.it





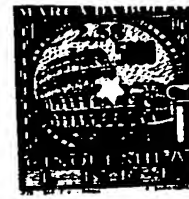
Con l'occasione Vi ricordiamo che il termine ultimo per poter provvedere alle fusi nazionali nei Paesi di Vostro interesse scadrà in data 18.10.2003.

Restando a Vostra disposizione per l'eventuale preparazione di preventivi di spesa ed in attesa di un Vostro cortese riscontro sui passi da intraprendere entro il 15.09.2003, con l'occasione porgiamo i nostri migliori saluti.

NOTARBARTOLO & GERVASI

 Maria Vittoria Primiceri

A.l.c.s.



[NOTAR BARTOLO & GERVASI LETTERHEAD]

[LIST OF PARTNERS AND ASSOCIATES]

JC17 Rec'd PCT/PTO 15 SEP 2005

Messrs

ISTITUTO SUPERIORE DI SANITA'
Financial Services
Division VIII – Contracts
C/o Doctor Martoccia
Viale Regina Elena 299
00161 ROME

STAMP – ISTITUTO SUPERIORE DI SANITA' –
ROME
043355 10 SEPT. 03
[ILLEGIBLE]

Milan, 08.09.2003

Re: International Patent Application N. PCT/EP02/04303

Deposited on the 18.04.2002

On behalf of "ISTITUTO SUPERIORE DI SANITA"

Bearing title: "Use of inhibitors of protease of the human immunodeficiency virus (HIV)

..."Inventor: Barbara ENSOLI

Our ref. 2770PTWO/er

With reference to the application in hand, we forward You a copy of the International Preliminary Examination Report issued on the 29.07.2003.

REDACTED

REDACTED

REDACTED

With the occasion, we remind You that the last date to provide for the national phases in the Countries of Your Interest will expire on the 18.10.2003.

Remaining at Your disposal for the preparation of any expense estimates and awaiting Your kind reply for the actions to be taken within the 15.09.2003, we send You our best regards.

NOTARBARTOLO & GERVASI
Maria Vittoria Primiceri
[Illegible Signature]

[A large, sweeping, handwritten flourish or signature line spans across the middle of the page.]



TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

CRONOLOGICO

N. ⁵ 6510

Roma, 9 GIU. 2005

Addi 9 GIU. 2005 avanti al sottoscritto Cancelliere è presente il

IL COLLABORATORE

Signor: GIANNINI Giurio

documento: P.A. N. RM6089390M

rilasciato da M.C.T.C. RM il 28/08/2002

il quale chiede di asseverare con giuramento il suesteso atto. Io
Cancelliere, previa ammonizioni di legge, invito il comparente al
giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente
adempiuto all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

[Handwritten signature]

DIRETTORE DI CANCELLERIA

(Giovanna Dionette)



[Handwritten signature of Giovanna Dionette]

APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da GIOVANNA DIONETTE

Agente in qualità di DIRETTORE DI CANCELLERIA

È segnato dal contrassegno/timbro Tribunale Ordinario di Roma

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma

in data 9 GIU. 2005 e sotto il N. 1225/3 del Reg. delle Apostille

con sigillo dell'Ufficio legalizzazioni.



IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE

Dott. Ferdinando Correale

[Handwritten signature of Dott. Ferdinando Correale]

10/549958

EXHIBIT C

JC17 Rec'd PCT/PTO 15 SEP 2005

Rossetti Elisa

Da: Cozzone Giovan Battista [cozzone@tin.it]
 Inviato: lunedì 15 settembre 2003 8.49
 A: Rossetti Elisa; Primiceri Maria Vittoria
 Cc: ensoli@iss.it; "Dott.ssa Rosa Martocchia"; Paola Sergiampletri; Paolo Monini
 Oggetto: Caso 2770PTWO (Patent PI)

Vi comunico che in data 23 settembre discuteremo (inventori e il sottoscritto) di una bozza di documento a risposta delle obiezioni re caso in oggetto. La data del 15 settembre è per noi improponibile; il documento definitivo sarà pronto, salvo imprevisti, entro il 25 di settembre.

Cordiali Saluti

Giovanni Cozzone
 Advisor del CdA in materia di strategia e gestione
 delle attività brevettuali e Technology Transfer
 ISTITUTO SUPERIORE DI SANITA'
 Tel: +39 347 782 9440
 Fax: +39 06 233 231 988

> > —Messaggio originale—

>> Da: Rossetti Elisa [mailto:e.rossetti@ngpatent.it]
 >> Inviato: lunedì 8 settembre 2003 15.05
 >> A: ensoli@iss.it
 >> Cc: cozzone@tin.it
 >> Oggetto: caso 2770PTWO

>> <<caso 2770PTWO lettera e IPER.PDF>>

>> Vi trasmettiamo in allegato la nostra lettera, che la Dr.ssa Martocchia
 >> riceverà oggi via fax, di commento al rapporto finale dell'Esaminatore a
 >> fronte del caso in oggetto.

>> Cordiali saluti.

>> Elisa Rossetti
 >> NOTARBARTOLO & GERVASI
 >> Corso di Porta Vittoria, 9
 >> 20122 Milan (Italy)

>> *+39 025417991
 >> *+39 0254179920
 >> mailto:notage@ngpatent.it
 >> mailto:e.rossetti@ngpatent.it

>>
 > Attachment converted: Macintosh HD:caso 2770PTWO lettera e I 1.PDF
 >(PDF /CARO) (001847F6)

er essere sottoposti alla valutazione del Consiglio di Amministrazione di ISS.

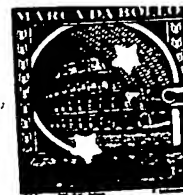


EXHIBIT 2

Rossetti Elisa

From: Cozzone Giovan Battista [cozzone@tin.it]

Sent: Monday, 15 September 2003, 08:49 a.m.

To: Rossetti Elisa; Primiceri Maria Vittoria

Cc: ensoli@iss.it; "Dr. Rosa Martoccia"; Paola Sergiampietri; Paolo Monini

Re: Case 2770PTWO (Patent PI)

I inform You that on the 23rd of September we (the inventors and myself) shall discuss a draft in reply to the objections raised against the case in question. The 15th of September is out of the question for us; the final document, circumstances permitting, will be ready within the 25th of September.

Yours sincerely

Giovanni Cozzone

Advosor of the Board of Directors as regards strategy and management of the patent activities and Technology Transfer

ISTITUTO SUPERIORE DI SANITA'

Tel.: +39 347 782 9440

Fax: +39 06 233 231 988

>> Original message

>> **From:** Rossetti Elisa [mailto: e.rossetti@ngpatent.it]

>> **Sent:** Monday, 8 September 2003 15:05 p.m.

>> **To:** ensoli@iss.it

>> **Cc:** cozzone@tin.it

>> **Re:** case 2770PTWO

>> <<case 2770PTWO, letter and IPER.PDF>>

>> We herein enclose our letter, that Dr. Martoccia will receive today via fax, commenting

>> the final report of the Examiner on the case in question.

>> Yours sincerely.

>> Elisa Rossetti

>> NOTARBARTOLO & GERVASI

>> Corso di Porta Vittoria, 9

>> 20122 Milan (Italy)

>> *+39 025417991

>> *+39 0254179920

>> mailto: notage@ngpatent.it

>> mailto: e.rossetti@ngpatent.it

> Attachment converted: Macintosh HD; case 2770PTWO letter and I 1.PDF

> (PDF/CARO) (001847F6)

To be submitted to the evaluation of the ISS Board of Directors.

Handwritten signature

TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

CRONOLOGICO

N. 2 8063

Roma, 12 106.2005

IL COLLABORATORE

Addi 12.10.2005..... avanti al sottoscritto Cancelliere è presente il

Signor: GIANNINI GIULIO.....

documento: PATENTE AUTO..... N. RM6089390M

rilasciato da MSE-RM..... il 28.08.2002.....

Il quale chiede di asseverare con giuramento il suesteso atto. Io

Cancelliere, previe ammonizioni di legge, invito il comparente al

giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente

adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

[Handwritten signature]



DIRETTORE DI CANCELLERIA
(Messa a disposizione)

[Handwritten signature]

APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da MARIA ANTONIETTA FRASZINO
Agente in qualità di DIRETTORE DI CANCELLERIA
È segnato dal contrassegno/timbro Tribunale Ordinario di Roma

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma
in data 12 LUG. 2005 e sotto il N. 1510/6 del Reg. delle Apostille
con sigillo dell'Ufficio legalizzazioni



IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE
Dott. Ferdinando Correale

A handwritten signature in dark ink, appearing to be "F. Correale", written over a horizontal line.

EXHIBIT D

10 / 549958

JC17 Rec'd PCT/PTO 15 SEP 2005

Rossetti Elisa

Da: Rossetti Elisa
Inviato: lunedì 22 settembre 2003 16:18
A: 'cozzone@tin.it'
Cc: 'ensoli@iss.it'; Primiceri Maria Vittoria
Oggetto: caso 2770PTWO



preventivo caso
2770PT.doc

Vi trasmettiamo in allegato il nostro preventivo per il caso in oggetto.

Cordiali saluti.

Elisa Rossetti
NOTARBARTOLO & GERVASI
Corso di Porta Vittoria, 9
20122 Milan (Italy)

*+39 025417991
*+39 0254179920
<mailto:notage@ngpatent.it>
<mailto:e.rossetti@ngpatent.it>

Spett.
ISTITUTO SUPERIORE DI SANITA'
Servizi Amministrativi
Divisione VIII - Contratti
c.a. Dr.ssa Martoccia
Viale Regina Elena 299
00161 ROMA

2

Milano, 22.09.2003

Oggetto: Domanda di Brevetto Internazionale N. PCT/EP02/04303
depositata il 18.04.2002
a nome ISTITUTO SUPERIORE DI SANITA'
dal titolo: "Use of inhibitors of protease of the human immunodeficiency virus (HIV)..."
Inventore: Barbara ENSOLI
Ns. rif. 2770PTWO/er

Con riferimento al caso in oggetto ed a seguito degli accordi telefonici intercorsi con il Dr. Cozzone in data 19.09.2003, Vi diamo il nostro preventivo per le fasi nazionali per gli stessi Paesi in cui era già stato depositato il precedente brevetto della Dr.ssa Ensoli, ns. caso 1354PT:

	Tasse ufficiali	Ns. onorario	Spese	Totale
REDACTED				

EXHIBIT 3
Rossetti Elisa



From: Rossetti Elisa

Sent: Monday, 22 September 2003 16:18 p.m.

To: cozzone@tin.it

Cc: ensoli@iss.it; Primiceri Maria Vittoria

Re: case 2770PTWO

[word doc.]

budget case 2770PT.doc

We herein enclose our budget for the case in question.

Yours sincerely,

Elisa Rossetti

NOTARBARTOLO & GERVASI

Corso di Porta Vittoria, 9

20122 Milan (Italy)

*+39 025417991

*+39 0254179920

[mailto: notage@ngpatent.it](mailto:notage@ngpatent.it)

[mailto: e.rossetti@ngpatent.it](mailto:e.rossetti@ngpatent.it)

SPAZIO NON UTILIZZABILE

FS

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

U.S.A.
"Small Entity"

REDACTED

REDACTED

REDACTED

REDACTED

REDACTED

Restiamo in attesa di ricevere Vostre cortesi istruzioni, entro e non oltre il 25.09.2003, in merito ai passi da intraprendere, con l'occasione porgiamo i nostri migliori saluti.

NOTARBARTOLO & GERVASI

Anna Gerli

[EXHIBIT 1]

**Messrs.
ISTITUTO SUPERIORE DI SANITA'
Administrative Affairs
Division VIII – Contracts
Care of Dr. Martocchia
Viale Regina Elena 299
00161 ROME
Milan, 22.09.2003**

Re: International Patent Application N. PCT/EP02/04303

Deposited on the 18.04.2002

On behalf of: ISTITUTO SUPERIORE DI SANITA'

Title: "Use of inhibitors of protease of the human immunodeficiency virus (HIV)... "

Inventor: Barbara ENSOLI

Our ref. 2770PTWO/er

With reference to the case on hand and following the telephone agreements exchanged with Dr. Cozzone on the 19.09.2003, we forward You our budget for the national phases for the same countries in which the previous patent of Dr. Ensoli was deposited, our case 1354PT:

[illegible]

REDACTED				
REDACTED				
U.S.A. "small entity"				

REDACTED

REDACTED

Awaiting Your kind instructions, within the 29.09.2003, as to the steps to be taken, we
send our best regards.

NOTARBARTOLO & GERVASI
Anna Gerli

TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

Addi 1.2.LUG.2005..... avanti al sottoscritto Cancelliere è presente il

Signor: GIANNINI GIULIO.....

documento: PATENTE AUTO..... N. RM6089390M

rilasciato da MSE-RM..... il 28.08.2002.....

Il quale chiede di asseverare con giuramento il suesposto atto. Io
Cancelliere, previa ammonizioni di legge, invito il comparente al
giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente
adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

[Handwritten signature]

DIRETTORE DI CANCELLERIA
[Handwritten signature]

APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da MARIA ANTONIETTA FRANZINO

Agente in qualità di DIRETTORE DI CANCELLERIA

È segnato dal contrassegno/limbro Tribunale Ordinario di Roma

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma

in data 1.2.LUG.2005 sotto il N. 1519/5 del Reg. delle Apostille

con sigillo dell'Ufficio legalizzazioni.

IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE
Dott. Ferdinando Corrales

CRONOLOGICO

N. 48063

Roma, 1.2.LUG.2005

IL COLLABORATORE



EXHIBIT E

10/549958

JC17 Rec'd PCT/PTO 15 SEP 2005

Gerli Anna

Da: Rossetti Elisa
 Inviato: martedì 30 settembre 2003 14.10
 A: Gerli Anna
 Oggetto: I: caso 2770PTWO

—Messaggio originale—

Da: Cozzone Giovan Battista [SMTP:cozzone@tin.it]
 Inviato: martedì 30 settembre 2003 14.04
 A: Rossetti Elisa
 Cc: BARBARA ENSOLI; Primiceri Maria Vittoria; "Dott.ssa Rosa Martocchia"
 Oggetto: Re: caso 2770PTWO

> <<preventivo caso 2770PT.doc>>
 >
 >Vi trasmettiamo in allegato il nostro preventivo per il caso in oggetto.
 >
 >Cordiali saluti.
 >
 >Elisa Rossetti
 >NOTARBARTOLO & GERVASI
 >Corso di Porta Vittoria, 9
 >20122 Milan (Italy)
 >
 >+39 025417991
 >+39 0254179920
 >mailto:notage@ngpatent.it
 >mailto:e.rossetti@ngpatent.it
 >
 >Content-Type: application/msword;
 > name="preventivo caso 2770PT.doc"
 >Content-Description: preventivo caso 2770PT.doc
 >Content-Disposition: attachment;
 > filename="preventivo caso 2770PT.doc"
 >
 >Attachment converted: Macintosh HD:preventivo
 >caso 2770PT.doc (WDBN/MSWD) (0018807C)

Gentile Dottoressa

Alla luce dei costi elevatissimi delle fasi nazionali, e per poter valutare in dettaglio le singole componenti di tali costi con l'obiettivo della loro riduzione per le occasioni future, le sarò grato se vorrà fornirmi i seguenti dati:

- A. Numero totale pagine del brevetto
- B. Numero totale pagine da disegno
- C) il breakdown dei costi denominati da N&G "Tasse ufficiali in:
 - a) costi traduzione per fase
 - b) tasse per fase

Cordiali Saluti

Giovanni Cozzone
 Advisor del CdA in materia di strategia e gestione
 delle attività brevettuali e Technology Transfer
 ISTITUTO SUPERIORE DI SANITA'
 Tel: +39 347 782 9440

Fax: +39 06 233 231



[EXHIBIT 5]
Gerli Anna

From: Rossetti Elisa

Sent: Tuesday, 30 September 2003 14:10 p.m.

To: Gerli Anna

Re: case 2770PTWO

- Original message -

From: Cozzone Giovan Battista [SMTP: cozzone@tin.it]

Sent: Tuesday, 30 September 2003 14:04 p.m.

To: Rossetti Elisa

Cc: BARBARA ENSOLI; Primiceri Maria Vittoria; "Dr. Rosa Martoccia"

Re: Re: case 2770PTWO

> <<budget case 2770PT.doc>>

> We herein enclose our budget for the case in question.

> Yours sincerely.

> Elisa Rossetti

> NOTARBARTOLO % GERVASI

> Corso di Porta Vittoria, 9

> 20122 Milan (Italy)

> *+39 02547991

> *+39 0254179920

> mailto: notage@ngpatent.it

> mailto: e.rossetti@ngpatent.it

> Content-Type: application/msword

> name = "budget case 2770PT.doc"

> Content-Description: budget case 2770PT.doc

> Content-Disposition: attachment

> filename: "budget case 2770PT.doc"

> Attachment converted: Macintosh HD: budget

> case 2770PT.doc (WDBN/MSWD) (00188070)

Dear Doctor,

In the light of the very high costs of the national phases, and in order to examine in detail each element of such costs to reduce them for future occasions, I would appreciate if You could kindly send us the following information:

A. Total number of pages of the patent

B. Total number of pages containing pictures

C. The breakdown of the costs called by N&G: "Official Taxes divided in:

a) translation costs per phase

b) taxes per phase

Yours sincerely

Giovanni Cozzone

Advisor of the Board of Directors as regards strategy and management of the patent activities and Technology Transfer

ISTITUTO SUPERIORE DI SANITA'

Tel.: +39 347 782 9440

Fax: +39006 233 231 988



TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

CRONOLOGICO

N. *1* 8063

Roma, 12 LUG. 2005

IL COLLABORATORE *[Signature]*

Addi *12* LUG. 2005, avanti al sottoscritto Cancelliere è presente il

Signor: *GIANNINI GIULIO*

documento: *PATENTE AUTO* N. *RM6089390M*

rilasciato da *MSE-RM* il *28.08.2002*

Il quale chiede di asseverare con giuramento il suesposto atto. Io

Cancelliere, previa ammonizioni di legge, invito il comparente al

giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente

adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

[Signature]



DIRETTORE DI CANCELLERIA
[Signature]



APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da MARIA ANTONIETTA FRANZINO

Agente in qualità di DIRETTORE DI CANCELLERIA

È segnato dal contrassegno/numero Tribunale Ordinario di Roma

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma

in data 12 LUG. 2005 è sotto il N. 1510/2 del Reg. delle Apostille

con sigillo dell'Ufficio legalizzazioni.



IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE
Dott. Ferdinando Correale

Stampa illeggibile e sfocata in basso a destra.

EXHIBIT F

10/549958

JC17 Rec'd PCT/PTO 15 SEP 2005

EXHIBIT 6

Gerli Anna

Da: Gerli Anna
Inviato: martedì 30 settembre 2003 14.18
A: 'cozzone@tin.it'
Oggetto: APreventivo caso 2770PT

Egregio Dr. Cozzone,

Sono in grado di fornirLe una risposta immediata alle prime sue domande come segue:

A. 59 PAGINE

B. 36 TAVOLE DA DISEGNO

Aggiungerò N. 26 RIVENDICAZIONI.

Per il terzo quesito dovrei riprendere di nuovo tutto il lavoro svolto in quanto il mio programma mi fornisce solo un totale e visto il brevissimo tempo a nostra disposizione per la predisposizione della fase nazionale (18 ottobre 2003) non sono in grado di soddisfarLa.

Cordiali saluti

Anna Gerli
NOTARBARTOLO & GERVASI
Corso di Porta Vittoria, 9
20122 Milan (Italy)

☎ +39 025417991

☎ +39 0254179920

✉ <mailto:notage@ngpatent.it>

✉ <mailto:a.gerli@ngpatent.it>



[EXHIBIT 6]
Gerli Anna

From: Gerli Anna

Sent: Tuesday, 30 September 2003, 14:18 p.m.

To: cozzone@tin.it

Re: ABudget case 2770PT

Dear Dr. Cozzone,

I can answer immediately Your first questions:

A. 59 PAGES

B. 36 PICTURES

I would add N. 26 CLAIMS.

To answer the third question, I should examine all the work carried out because my programme supplies me only one total, and considering the very short time at disposal for the preparation of the national phase (18th of October 2003), I cannot satisfy Your request.

Yours sincerely

Anna Gerli

NOTARBARTOLO & GERVASI

Corso di Porta Vittoria, 9

20122 Milan (Italy)

Tel.: +39 025417991

Fax: +39 0254179920

[mailto: notage@ngpatent.it](mailto:notage@ngpatent.it)

[mailto: a.gerli@ngpatent.it](mailto:a.gerli@ngpatent.it)

Anna

TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

Addi 1-2-11-6-2005..... avanti al sottoscritto Cancelliere è presente il

Signor: GIANNINI GIULIO.....

documento: PATENTE AUTO..... N. RM 6089390M

rilasciato da MTC-RM..... il 28.08.2002.....

Il quale chiede di asseverare con giuramento il suesteso atto. Io

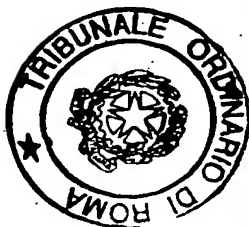
Cancelliere, previe ammonizioni di legge, invito il comparente al

giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente

adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

Giulio Giannini



DIRETTORE DI CANCELLERIA
Maria Antonietta...

CRONOLOGICO

N. 5 8063

Roma, 12-11-6-2005

IL COLLABORATORE

[Signature]



APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da MARIA ANTONIETTA FRANZINO

Agente in qualità di DIRETTORE AL CANCELLERIA

Tribunale Ordinario di Roma

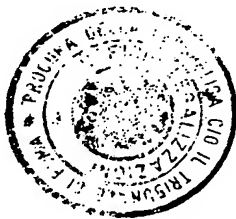
È segnato dal contrassegno/timbro

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma

in data **12 LUG. 2005** e sotto il N. 1512/3 del Reg. delle Apostille

con sigillo dell'Ufficio legalizzatori.



IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE
Dott. Ferdinando Correale

[Faint, illegible text at the bottom of the page]

EXHIBIT G

10 / 549958

JC17 Rec'd PCT/PTO 15 SEP 2005

Gerli Anna

Da: Gerli Anna
Inviato: mercoledì 1 ottobre 2003 8.17
A: 'Cozzone Giovan Battista'
Oggetto: R: APreventivo caso 2770PT

Egregio Dr. Cozzone,
Farò il possibile per soddisfare le Sue richieste; nel frattempo Le sarei grata se potesse darci la conferma dei Paesi perchè, soprattutto per quelli a traduzione, potremmo correre il rischio di non riuscire a rispettare i termini, vista anche l'ampiezza del testo.
Grazie e cordiali saluti.
Anna Gerli

—Messaggio originale—

Da: Cozzone Giovan Battista [SMTP:cozzone@tin.it]
Inviato: mercoledì 1 ottobre 2003 6.00
A: Gerli Anna
Cc: "Dott.ssa Rosa Martocchia"; BARBARA ENSOLI
Oggetto: Re: APreventivo caso 2770PT

Gentile Dottoressa,

la ringrazio per le risposte riportate dabbasso; per ciò che concerne il resto, non è necessario che Lei invii il breakdown entro il 18 ottobre; per la fine di ottobre va bene?

Come sottolineato nel mio email i dati ci servono per il futuro non per il problema contingente.

Cordiali Saluti

Giovanni Cozzone
Advisor del CdA in materia di strategia e gestione
delle attività brevettuali e Technology Transfer
ISTITUTO SUPERIORE DI SANITA'
Tel: +39 347 782 9440
Fax: +39 06 233 231.988

Egregio Dr. Cozzone,
Sono in grado di fornirLe una risposta immediata alle prime sue domande come segue:
A. 59 PAGINE
B. 36 TAVOLE DA DISEGNO
Aggiungerei N. 26 RIVENDICAZIONI

Per il terzo quesito dovrei riprendere di nuovo tutto il lavoro svolto in quanto il mio programma mi fornisce solo un totale e visto il brevissimo tempo a nostra disposizione per la predisposizione della fase nazionale (18 ottobre 2003) non sono in grado di soddisfarLa.
Cordiali saluti

Anna Gerli
NOTARBARTOLO & GERVASI
Corso di Porta Vittoria, 9

20122 Milan (It)

*+39 025417991

*+39 0254179920

* <mailto:notage@ngpatent.it>

* <mailto:a.gerli@ngpatent.it>



[EXHIBIT 7]
Gerli Anna

From: Gerli Anna

Sent: Wednesday, 1 October 2003, 08:17 a.m.

To: "Cozzone Giovan Battista"

Re: R: ABudget case 2770PT

Dear Dr. Cozzone,

I will do my best to satisfy Your requests: in the meantime, I would be glad if You could confirm the Countries, especially the ones to be translated, because we could risk to fail to respect the deadlines considering also the bulk of the text.

Thank you,

Yours sincerely

Anna Gerli

- Original message -

From: Cozzone Giovan Battista [SMTP: cozzone@tin.it]

Sent: Wednesday, 1 October 2003, 08:00 a.m.

To: Gerli Anna

Cc: "Dr. Rosa Martoccia"; BARBARA ENSOLI

Re: Re: ABudget case 2770PT

Dear Doctor,

Thank You for the answers that You kindly supplied; as far as the rest is concerned, You do not have to send me the breakdown within the 18th of October, would the end of October be fine with You?

As I pointed out in my email, the information requested is needed for the future and not for the current problem.

Yours sincerely

Giovanni Cozzone

Advisor of the Board of Directors as regards strategy and management of the patent activities and Technology Transfer

ISTITUTO SUPERIORE DI SANITA'

Tel.: +39 347 782 9440

Fax: +39006 233 231 988

Dear Dr. Cozzone,

I can answer immediately Your first questions:

A. 59 PAGES

B. 36 DRAWING TABLES

I would add N. 26 CLAIMS.

To answer the third question, I should examine all the work carried out because my programme supplies me only one total, and considering the very short time at disposal for the preparation of the national phase (18th of October 2003) I cannot satisfy Your request.

Yours sincerely

Anna Gerli

NOTARBARTOLO & GERVASI

Corso di Porta Vittoria, 9

20122 Milan (Italy)

Tel.: +39 025417991

Fax: +39 0254179920

[mailto: notage@ngpatent.it](mailto:notage@ngpatent.it)

[mailto: a.gerli@ngpatent.it](mailto:a.gerli@ngpatent.it)

TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

8063

Addi avanti al sottoscritto Cancelliere è presente il

Signor: GIANNINI GIULIO.....

documento: PATENTE AUTO..... N. RM.6089390M

rilasciato da: MSIC-RM..... il 28.08.2002.....

Il quale chiede di asseverare con giuramento il suesteso atto. Io

Cancelliere, previe ammonizioni di legge, invito il comparente al

giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente

adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

[Handwritten signature]



IL DIRETTORE IN CANCELLERIA
Maria Antonietta Frattolillo

[Handwritten signature]

CRONOLOGICO

N. 68063

Roma, 12 LUG. 2005

IL COLLABORATORE

[Handwritten signature]

APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da MARIA ANTONIETTA FRANZINO
Agente in qualità di DIRETTORE AL CANCELLERIA
È segnato dal contrassegno/timbro Tribunale Ordinario di Roma

ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma
in data 12 LUG. 2005 e sotto il N. 1510/4 del Reg. delle Apostille
con sigillo dell'Ufficio legalizzazioni.

IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE
Dott. Ferdinando Correale



MINISTERO DELLA GIUSTIZIA
DIREZIONE REGIONALE DEL TRAPIANO
ROMA

EXHIBIT H

10/549958

JC17 Rec'd PCT/PTO 15 SEP 2005

30/10/2003

To: "Paola Sergiampietri" <sgpietri@iss.it>, "Dott.ssa Rosa Martoccia":dirghensa@iss.it, monica.nusca@iss.it;, BARBARA ENSOLI <ensoli@iss.it>
From: Cozzone Giovan Battista <cozzone@tin.it>
Subject: Re: PATENT PI (Rif. N&G: 2770PTWO/er)
Cc:
Bcc:

Sull'ultimo punto, suggerisco affidare la fase nazionale USA a Pennie & Edmunds.

Giovanni Cozzone

> -----Messaggio originale-----
> Da: Gerli Anna [mailto:a.gerli@ngpatent.it]
> Inviato: giovedì 30 ottobre 2003 15.43
> A: Barbara Ensoli
> Cc: Primiceri Maria Vittoria
> Oggetto: R: PATENT PI (Rif. N&G: 2770PTWO/er)
> Priorità: Alta
>
>
> Gentile Dr.a Sergiampietri,
> Con riferimento alla sua e-mail del 27 corr. desideriamo precisare quanto
> segue:
> 1) non abbiamo mai ricevuto da Voi alcuna lettera datata 30.9.2003 e
neppure
> successive comunicazioni
> 2) in data 20 ottobre abbiamo ricevuto da parte dei Vostri Uffici
> Amministrativi la lettera da Voi indicata con richiesta di un preventivo
più
> dettagliato
> 3) in data 23 ottobre via fax "Contratto di affidamento incarico" da parte
> dei Vostri Uffici Amministrativi
> ciò premesso ci siamo subito attivati per il deposito delle fasi nazionali
> nei Paesi cui Vostro elenco.
> A questo riguardo e con riferimento alla sua e-mail del 29-10-2003
> indirizzata alla Dr.a Primiceri facciamo presente quanto segue:
> 1) la domanda di Brevetto Europeo (con termine 31 mesi) verrà estesa
anche

> ai seguenti Paesi: Albania, Romania, Slovenia, Lituania, Lettonia, Macedonia

> per quanto riguarda Repubblica Ceca, Repubblica Slovacca, Bulgaria,

> Estonia ed Ungheria (con termine 31 mesi) abbiamo già passato istruzioni ai

> nostri

> corrispondenti di procedere

> 2) Della Convenzione OAPI fanno parte anche Guinea Bissau e Guinea Equatoriale (termine 30 mesi)

> 3) Della Convenzione ARIPO fanno parte anche Mozambico, Sierra Leone e Zambia (termine 31 mesi)

> 4) La Turchia fa parte della Convenzione Europea (termine 31 mesi)

> Per quanto riguarda infine la preparazione di un preventivo analitico Vi

> preghiamo di voler pazientare sino alla prossima settimana.

> Con l'occasione vorremmo altresì che ci precisaste se per il deposito in

> U.S.A. dovremo appoggiarci all'Ufficio Brevetti P&E, a cui è stata girata la

> gestione della Vostra precedente domanda (ns. rif. 1354PTUS). Vi facciamo

> presente che la questione riveste particolare urgenza in quanto il termine

> per gli U.S.A. è a 30 mesi con recupero mediante una Petition e pagamento di

> una sovrattassa.

> Cordiali saluti

>

>

> > -----Messaggio originale-----

> > Da: Barbara Ensoli [SMTP:ensoli@iss.it]

> > Inviato: lunedì 27 ottobre 2003 14.41

> > A: Ng-roma; Gerli Anna

> > Cc: Primiceri Maria Vittoria; Giovanni Cozzone

> > Oggetto: PATENT PI (Rif. N&G: 2770PTWO/er)

> > Priorità: Alta

> >

> > Oggetto: Domanda di brevetto internazionale n. PCT/EP02/04303 del

> 18.04.2002 -

> >

> > Inventore: Dr. Barbara Ensoli - Rif. N&G: 2770PTWO/er

> >

> >

> >

> >

> > Gent.le Dr. Gerli,

> >

> >

> >

> > Ad integrazione della ns. lettera del 30/9/2003 e a seguito delle

> intercorse comunicazioni, si ribadisce l' > > intenzione a proseguire con

le

- > fasi nazionali inerenti il brevetto in oggetto.
- > >
- > >
- > >
- > > A tal fine, considerata l'> 'urgenza e l'> 'importanza di proseguire con
- > procedimenti di nazionalizzazione, si notifica nuovamente la designazione di
- > tutti i paesi riportati nella lista inviata con nostra autorizzazione a
- > procedere del 30 Settembre c.a. (e lettera dei competenti uffici
- > amministrativi del 14/10/2003, Prot. N. 49602/RE67).
- > >
- > >
- > >
- > > Si richiede con urgenza alla N&G SpA l'> 'indicazione dei costi
- > sostenibili per l'> 'estensione alle fasi nazionali nei sottoelencati paesi
- > (attualmente non contemplati nel prospetto della N&G inviatoci il 22
- > Settembre 2003):
- > >
- > >
- > >
- > > EP: Albania, Repubblica Ceca, Repubblica Slovacca, Romania, Slovenia,
- > Bulgaria, Estonia, Ungheria, Latvia, Lituania, Macedonia
- > >
- > > OAPI: Guinea Equatoriale, Guinea Bissau
- > >
- > > ARIPO: Mozambico, Sierra Leone, Zambia
- > >
- > > Altri: Turchia
- > >
- > >
- > >
- > > Si richiede gentilmente conferma della loro effettiva appartenenza ai
- > gruppi specificati nella lista da noi preventivamente inviata alla Vs.
- > attenzione
- > >
- > >
- > >
- > > In seconda istanza restiamo in attesa di un preventivo analitico avendo
- > cura che nella sua formulazione siano riportate le seguenti specifiche:
- > >
- > >
- > >
- > > - Numero totale pagine del brevetto
- > >
- > > - Numero totale figure

> >
 > > - Lista dei costi, con suddivisione degli oneri per > "> tasse
 > ufficiali> "> in: > "> costi traduzione per fase> "> e > "> tasse per
 > fase> "> .
 > >
 > >
 > >
 > > Tale preventivo dovrebbe essere formulato facendo riferimento al
 prospetto
 > dei paesi precedentemente da noi trasmesso e nuovamente alleato alla
 > presente. In merito ai punti sopraelencati giungerà, alla Sua attenzione,
 > ulteriore comunicazione dei competenti uffici amministrativi.
 > >
 > >
 > >
 > > In attesa di riscontro
 > >
 > >
 > >
 > > Cordiali saluti
 > >
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 > >
 > >
 > >
 > >
 > > Sergiampietri Paola
 > >
 > > Segreteria
 > >
 > >
 > >
 > >
 > >
 > > Dr. Barbara Ensoli
 > >
 > > Laboratorio di Virologia
 > >
 > > Istituto Superiore di Sanità
 > >
 > > V.le Regina Elena, 299
 > >
 > > 000161 Roma
 > >
 > > Tel: +39-06-49903209
 > >
 > > Fax: +39-06-49903002

> >
> > E-mail: ensoli@iss.it <mailto:ensoli@iss.it>
> > << File: Fasi.naz.PI_EP02=04303.xls >>
>

--

Best Regards

Sincerely,

Giovanni Cozzone, CEO
<http://www.help-finance.com>
by BEI Srl.
Via Montopoli, 4
00199, Roma

Tel: ++39.347.782.9440
Fax: +39.06.233.231.988
Email: vcnet@help-finance.com

6/11/2003

To: "Rossetti Elisa" <e.rossetti@ngpatent.it>
From: Cozzone Giovan Battista <cozzone@tin.it>
Subject: Re: I: PATENT PI (Rif. N&G: 2770PTWO/er)
Cc: "Dott.ssa Rosa Martoccia":dirghensa@iss.it, monica.nusca@iss.it;; BARBARA ENSOLI <ensoli@iss.it>, Paola Sergiampietri <sgpietri@iss.it>
Bcc:

gentile Dott.ssa

Ho già informato ISS che ritengo opportuno utilizzare Pennie & Edmunds anche per questo caso e credo che riceverete comunicazione a tal fine dall'Amministrazione oggi.

Cordiali Saluti

Giovanni Cozzone
Advisor del CdA in materia di strategia e gestione
delle attività brevettuali e Technology Transfer
ISTITUTO SUPERIORE DI SANITA'
Tel: +39 347 782 9440
Fax: +39 06 233 231 988

Facendo seguito al precedente messaggio, Vi rammentiamo che siamo ancora in attesa di conoscere il nominativo dell'agente USA al quale spedire l'incarico per la fase nazionale del suddetto caso.

Cordiali saluti

Elisa Rossetti
NOTARBARTOLO & GERVASI
Corso di Porta Vittoria, 9
20122 Milan (Italy)

tel.+39 025417991
fax+39 0254179920
mailto:notage@ngpatent.it
mailto:e.rossetti@ngpatent.it



30/10/2003

To: "Paola Sergiampietri" <sgpietri@iss.it>, "Dott.ssa
Rosa Martoccia": dirghensa@iss.it,
monica.nusca@iss.it;, BARBARA ENSOLI
<ensoli@iss.it>

From: Cozzone Giovan Battista <cozzone@tin.it>

Subject: Re: PATENT PI (Rif. N&G: 2770PTWO/er)

Cc:

Bcc:

As far as the last point is concerned, my advise is to
entrust the U.S.A. national phase to Pennie &
Edmunds.

Giovanni Cozzone

[ORIGINAL MESSAGE]

From: Gerli Anna [mailto:a.gerli@ngpatent.it]

Sent: Thursday 30th of October 2003 15.43

To: Barbara Ensoli

Cc: Primiceri Maria Vittoria

Object: R: PATENT PI (Ref. N&G: 2770PTWOO/er)

Priority: High

Dear Doctor Sergiampietri,

with reference to Your e-mail of the 27th of this
month, we wish to define precisely the following
details:

- W. G. S. e.*
- 1) we never received any letter dated 30/09/2003 from You, nor any following communications;
 - 2) on the 20th of October we received the letter You indicated with the request of a more detailed estimate from Your Administrative Office;
 - 3) we received on the 23rd of October, via fax, the "Commission assignment contract" from Your Administrative Office; that being stated, we immediately began to work on the deposit for the national phases in the Countries You included in Your list.

In this respect and with reference to Your e-mail of the 29-10-2003 addressed to Doctor Primiceri, we remind the following:

- 1) the European Patent application (with expiry within 31 months) will be extended also to the following Countries: Albania, Rumania, Slovenia, Lithuania, Latvia, Macedonia; as far as the Czech Republic, the Slovenian Republic, Bulgaria, Estonia and Hungary are concerned, (with expiry within 31 months) we already instructed our correspondents to proceed;
- 2) also Guinea Bissau and Equatorial Guinea belong to the OAPI Convention (expiry within 30 months);
- 3) also Mozambique, Sierra Leon and Zambia belong

brw&ie

- to the ARIPO Convention (expiry 31 months);
- 4) Turkey is not part of the European Convention (expiry 31 months).

And finally, as far as the drafting of an analytical estimate is concerned, we beg You to wait until next week.

We seize the opportunity to ask You to specify if we must rely on P&E's Patent Office for the deposit in the U.S.A., to whom You transferred the management of Your previous application (our ref. 1345PTUS).

We remind You that this subject is extremely urgent because the expiry for the U.S.A. is of 30 months with a recovery through Petition and the payment of an additional tax.

Yours sincerely.

[ORIGINAL MESSAGE]

From: Barbara Ensoli

Sent: Monday, 27th of October 2003 14.41

To: Ng-roma; Gerli Anna

Cc: Primiceri Maria Vittoria; Giovanni Cozzone

Object: PATENT PI (Ref. N&G: 2770PTWOO/er)

Priority: High

Object: International patent application n.

PCT/EP02/04303 of the 18/04/2002

Inventor: Doctor Barbara Ensoli - Ref. N&G:
2770PTWO/er

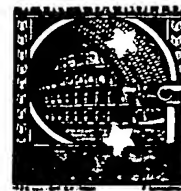
Dear Doctor Gerli,

As an integration to our letter of the 30/09/2003 and following the communications exchanged, we confirm our intention to proceed with the national phases concerning the patent in question.

In this order, keeping in due consideration the urgency and the importance to pursue the nationalisation procedures, we deem it necessary to notify again the designation of all the countries reported in the list sent together with our authorisation to proceed of the 30th of September of this year (and also the letter of the competent Administrative Office of the 14/10/2003, Reg. N. 49602/RE67).

N&G S.p.A. is urgently required to notify the costs expected for the extension of the national phases in the following countries (at present they are not included in N&G's report sent on the 22nd of September 2003).

EP: Albania, Czech Republic, Slovak Republic, Rumania, Slovenia, Bulgaria, Estonia, Hungary, Latvia, Lithuania, Macedonia;



to write

OAPI: Equatorial Guinea, Guinea Bissau;

ARIPO: Mozambique, Sierra Leon, Zambia;

Others: Turkey.

You are kindly requested to confirm their effective belonging to the groups specified in the list that we sent in advance to Your attention.

We also await an analytical estimate in which you must include the following specifications:

- total number of pages constituting the patent;
- total number of figures;
- list of costs, with the division of the costs in "official taxes" in: "translation costs per phase" and "phase costs".

This estimate should be formulated with reference to the report to the report of the countries that we sent previously and enclosed again herein.

As to the aforementioned points, the competent administrative office will send to Your attention further communications.

Awaiting Your kind reply,

Yours sincerely.

Sergimpietri Paola

SECRETARY

Doctor Barbara Ensoli

Laboratory of Virology

Ensol

Istituto Superiore di Sanità

V.la Regina Elena, 299

00161 ROMA

Tel.: + 39-06-49903209

Fax: + 39-06-49903002

E-mail: ensoli@iss.it [mailto:ensoli@iss.it]

File: Nat. Phases PI_EP02=04303.xls

Best regards

Sincerely,

Giovanni Cozzone, CEO

<http://www.help-finance.com>

by BEI Srl.

Via Montopoli, 4

00199, Rome

Tel.: + 39.347.782.9440

Fax: + 39.06.233.231.988

Email: vcnet@help-finance.com

6/11/2003

To: "Rossetti Elisa" <e.rossetti@ngpatent.it>

From: Cozzone Giovan Battista <cozzone@tin.it>

Subject: Re: I: PATENT PI (Rif. N&G:
2770PTWO/er)

Cc: "Dott.ssa Rosa Martoccia":dirghensa@iss.it,
monica.nusca@iss.it; BARBARA ENSOLI

Handwritten signature and arrow pointing to the email address
<ensoli@iss.it>, Paola Sergiampietri

<sgpietri@iss.it>

Bcc:

Dear Doctor,

I have already informed ISS that I deem the use of Pennie & Edmunds appropriate even in this case and I think that you will receive the communication concerning this subject from the Management today.

Yours sincerely

Giovanni Cozzone

Advisor of the Board of Directors of strategy and management of the patent activities and Technology Transfer

ISTITUTO SUPERIORE DI SANITA'

Tel: +39 347 782 9440

Fax: +39 06 233 231 988

Following the previous message, we remind You that we are still awaiting the name of the agent in the U.S.A. to whom we must send the commission of the national phase of the aforementioned case.

Yours sincerely.

Elisa Rossetti

NOTARBARTOLO & GERVASI

Corso di Porta Vittoria, 9-20122 Milan (Italy)

File

Tel.: + 39.025417991-Fax: + 39. 02541179920
mailto: notage@ngpatent.it
mailto: e.rossetti@ngpatent.it

TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

CRONOLOGICO

5297

N.
12 MAG. 2005

Roma,

Addi**4.2. MAG. 2005**... avanti al sottoscritto Cancelliere è presente il

IL COLLABORATORE *R*

Signor: **GIANNINI GIULIO**.....

documento: **PATENTE AUTO**..... N. **RM. 6089390M**

rilasciato da: **MCTC-RM**..... il **28.08.2002**...

Il quale chiede di asseverare con giuramento il suesposto atto. Io
Cancelliere, preve ammonizioni di legge, invito il comparente al
giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente
adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.

File

IL FUNZIONARIO DI CANCELLERIA
Dot. Vito Lancetti



EXHIBIT I

10 / 549958

JC17 Rec'd PCT/PTO 15 SEP 2005



Istituto Superiore di Sanità

DIREZIONE DEGLI AFFARI AMMINISTRATIVI
E DELLE RISORSE ECONOMICHE

6 NOVEMBRE 2003
00161 Roma,

VIALE REGINA ELENA, 299
TELEGRAMMI: ISTISAN ROMA
TELEFONO: 06 48801
TELEFAX: 06 48387118
<http://www.iss.it>

Notarbartolo & Gervasi S.p.A.
Corso di Porta Vittoria n. 9
20122 MILANO

e p.c. Dott.ssa Barbara Ensoli
Laboratorio di Virologia
Sede

N. 53852/RE 67

Risposta al Foglio del

N.

Allegati

OGGETTO: domanda di brevetto internazionale n. PCT/EP02/04303 del 18.04.2002 dal titolo "Use of inhibitors of protease of the Human immunodeficiency virus (HIV) ..." - inventore: Dott.ssa Barbara Ensoli.
Vs. Rif. 2770PTWO/er

Con riferimento al brevetto indicato in oggetto, si comunica che, in considerazione di quanto comunicato nell'e-mail dalla Dott. Gerli in data 30.10.2003, questo Istituto, in base alle determinazioni della dott.ssa Ensoli (inventore), comunica quanto segue.

la Notarbartolo & Gervasi S.p.A. dovrà provvedere all'avvio delle fasi nazionali nei paesi seguenti: European Patent (EP), Eurasian Patent (EA), ARIPO, Australia, Brasile, Canada, Cina, Cuba, Israele, Giappone, Messico, Nuova Zelanda, Polonia, Singapore, Sri Lanka, Turchia.

Resta escluso l'incarico relativo alla nazionalizzazione negli USA che sarà affidato alla Pennie & Edmonds direttamente da questo Istituto.

Codesto studio è cortesemente pregato di restituire debitamente sottoscritte, per accettazione, due copie della presente nota entro tre giorni dalla ricezione della stessa.

Si ricorda che i due esemplari dovranno essere sottoscritti dal legale rappresentante della Società.

Si resta in attesa di un cortese cenno di riscontro.

IL DIRETTORE DEGLI AFFARI AMMINISTRATIVI
E DELLE RISORSE ECONOMICHE
(Dr.ssa R.M. MARTOCCIA)



ISS STAMP

STAMP

ISTITUTO SUPERIORE DI SANITA'
DIRECTION OF ADMINISTRATIVE AFFAIRS AND
ECONOMIC RESOURCES

00161 ROME, 6TH OF NOVEMBER 2003

VIALE REGINA ELENA, 288

TELEGRAMS: ISTISAN ROMA

TELEPHONE: 06 48801

FAX: 06 48387118

<http://www.iss.it>

Notarbartolo & Gervasi S.p.A.

Corso di Porta Vittoria n. 9

20122 MILAN

copy to Doctor Barbara Ensoli

Laboratory of Virology

Head Office

N.: 53852/RE67


REPLY TO THE NOTE OF THE: [...]

N.: [...]

ENCLOSURES: [...]

OBJECT: International patent application n.
PCT/EP02/04303 of the 18/04/2002 bearing the name:
"Use of inhibitors of protease of the Human
immunodeficiency virus (HIV) ..." – Inventor: Doctor
Barbara Ensoli.

Your Ref. 2770TWO/er.



With reference to the patent stated in the object, we notify that, in consideration of the information included in Doctor Gerli's e-mail dated 30.10.2003, this Institute, in accordance with Doctor Ensoli's (inventor) determinations, states the following:

"Notarbartolo & Gervasi S.p.a." will be entrusted with the starting of the national phases in the following Countries: European Patent (EP), Eurasian Patent (EA), ARIPO, Australia, Brazil, Canada, China, Cuba, Israel, Japan, Mexico, New Zealand, Poland, Singapore, Sri Lanka, Turkey.

The commission concerning the nationalisation in the U.S.A. is not included because this Institute will entrust it directly to Pennie & Edmonds.

Your office is kindly required to return, for acceptance, two duly signed copies of the document herein within three days from its receipt.

We remind You that the two copies mentioned must be signed by the legal representative of the Company.

Awaiting Your kind reply,

**THE DIRECTOR OF THE ADMINISTRATIVE
AFFAIRS AND OF THE ECONOMIC RESOURCES**

[SIGNED]

Doctor R. M. Martoccia

TRIBUNALE DI ROMA

Ufficio Atti Notori - Perizie e Traduzioni

VERBALE DI GIURAMENTO

Addi 21/03/2005..... avanti al sottoscritto Cancelliere è presente il

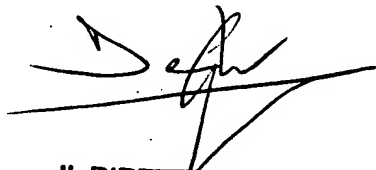
Signor: DANILO GIANNINI.....

documento: CARTA D'IDENTITA'..... N. AR 8753070.....

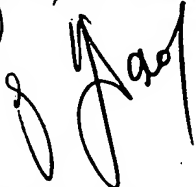
rilasciato da COMUNE DI ROMA..... il 21/01/2005.....

Il quale chiede di asseverare con giuramento il suesteso atto. Io
Cancelliere, preve ammonizioni di legge, invito il comparente al
giuramento, che egli presta ripetendo: "Giuro di avere bene e fedelmente
adempito all'incarico affidatomi al solo scopo di far conoscere la verità".

Letto, confermato e sottoscritto.



IL DIRETTORE DI CANCELLERIA
(Giovanna Dionette)



APOSTILLE

Convention de la Haye du 5 octobre 1961

REPUBBLICA ITALIANA

Il presente atto è stato sottoscritto da GIOVANNA DIONETTE

Agente in qualità di DIRETTORE DI CANCELLERIA

Tribunale Ordinario di Roma

È segnato dal contrassegno/timbro

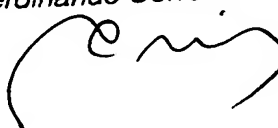
ATTESTATO

dalla Procura della Repubblica presso il Tribunale Ordinario di Roma

in data 21 MAR. 2005 e sotto il N. 592/3 del Reg. delle Apostille

con sigillo dell'Ufficio legalizzazioni.

IL FUNZIONARIO ABILITATO ALLA LEGALIZZAZIONE
Dott. Ferdinando Correale



CRONOLOGICO

N. 1 **3155**

Roma, 21 MAR. 2005

IL COLLABORATORE

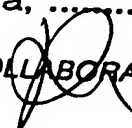


EXHIBIT J

10/549958

JC17 Rec'd PCT/PTO 15 SEP 2005

JONES DAY

222 EAST 41ST STREET • NEW YORK, NEW YORK 10017-6702
TELEPHONE: 212-326-3939 • FACSIMILE: 212-755-7306

March 1, 2005

Direct Number: (212) 326-3876
MBBrivanlou@joneday.com

By E-mail

Our Ref.: 11340-008-999 (CAM No. 406839-999008)

Dr. Giovanni Cozzone
Board Advisor for Intellectual Property & Technology Transfer
Istituto Superiore Di Sanita
Viale Regina Elena 299
00161, Roma
ITALY

Re: Dr. Ensoli's patent applications relating to:

REDACTED

REDACTED

3. International Application No. PCT/EP02/04303

**Title: USE OF INHIBITORS OF THE PROTEASE OF THE
HUMAN IMMUNODEFICIENCY VIRUS (HIV) TO
BLOCK CELL MIGRATION AND/OR INVASION, TISSUE
INFILTRATION AND OEDEMA FOR THE THERAPY OF
DISEASES ASSOCIATED THEREWITH**

Our ref.: 11340-007-228

REDACTED

Dear Giovanni:

We are pleased to inform you that we have received from Notarbartolo & Gervasi copies of their files in connection with the above-identified international patent applications by Dr. Ensoli. Enclosed is a copy of a Patent Report that lists the application information and our corresponding file number for Dr. Ensoli's patent applications.

Dr. Giovanni Cozzone
March 1, 2005
Page 2

JONES DAY

After reviewing the files for Dr. Ensoli's patent applications in detail, we noted the following upcoming due dates:

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Dr. Giovanni Cozzone
March 1, 2005
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JONES DAY

REDACTED

REDACTED

REDACTED

Dr. Giovanni Cozzone
March 1, 2005
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REDACTED

Dr. Giovanni Cozzone
March 1, 2005
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REDACTED

Dr. Giovanni Cozzone
March 1, 2005
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REDACTED

Dr. Giovanni Cozzone
March 1, 2005
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REDACTED

Dr. Giovanni Cozzone
March 1, 2005
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REDACTED

REDACTED

REDACTED

Dr. Giovanni Cozzone
March 1, 2005
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REDACTED

REDACTED

REDACTED

Dr. Giovanni Cozzone
March 1, 2005
Page 10

JONES DAY

REDACTED

REDACTED

It is our understanding that no U.S. application has been filed in connection with International Application No. PCT/EP02/04303. If this is not true, please kindly let us know the corresponding U.S. patent application number.

REDACTED

Sincerely,



Margaret B. Brivanlou

Enclosure

cc: Dr. Barbara Ensoli
Adriane M. Antler, Esq.
Ann W. Chen, Esq.

EXHIBIT K

10/549958

JC17 Rec'd PCT/PTO 15 SEP 2003

REDACTED

REDACTED

Cozzone Giovan Battista <cozzone@tin.it>



Cozzone Giovan Battista
<cozzone@tin.it>

03/28/2005 03:34 PM

To "Adriane Antler" <amantler@JonesDay.com>
cc carinci@iss.it, stefania.ceccarelli@iss.it, Barbara Ensoli
<ensoli@iss.it>
Subject RE AFFIDATIVIT PI FOR USA

Adriane

as explained by phone, the fact that the subject patent was not filed in the USA along with all other national phases is the result of a fatal problem in communications with the administrative offices of the Italian NIH (Istituto Superiore di Sanità or ISS) .

As evidenced by the documents (email messages and letters from the administration of ISS) and respective english translations, - to be shortly forwarded to you - I instructed ISS to inform their patent firm , Notarbartolo & Gervasi, who had been soliciting a response on the USA filing, to appoint Jones Day (at the time Pennie & Edmunds) as the US correspondent to handle the filing.

This decision was consistent with the previous one to appoint P&E to handle other patent cases for Dr. Ensoli **REDACTED** the inventor for the subject case.

ISS administration erroneously interpreted my instructions and instead asked Notarbartolo & Gervasi to file everywhere else except in the USA where - and this was the fatal error - ISS would proceed to file directly.

Even if doable, and I don't know if it is, this would have never been possible simply due to the fact that ISS does not have an in house patent attorney who would be able to handle this.

Unfortunately I was not copied in the instruction letter to Notarbartolo & Gervasi and learned of

this situation only very recently from your status update on pending annuities and office actions.

Please let me know if I should write an affidavit and if I should have my signature verified it in the US Embassy in Rome .

Giovanni

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